# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

071737444

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 071738020 071738608 071891258 078289800 078291200 078291900

MSDS Name: IRM POWDER & LIOUID

Kit Components:

510896 : IRM POWDER

510897 : IRM Liquid Zinc Oxide Eugenol

Dentsply Caulk

IRM Liquid Zinc Oxide Eugenol Manufacturer MSDS Number: 510897NFPA

> 1 2 0

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 1 : Chemical Product and Company Identification

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

MSDS Name: IRM Liquid Zinc Oxide Eugenol

Manufacturer Name: Dentsply Caulk

Address:

38 West Clarke Avenue Milford DE 19963-0359

Internet Address: http://www.caulk.com

Business Phone: (302) 422-4511

For information in North America, call: (302) 422-4511 For emergencies in the US, call CHEMTREC: 800-424-9300 Hours Of Operation: (8:00 AM - 4:30 PM Eastern Time)

Manufacturer MSDS Creation Date:

11/13/98

Manufacturer MSDS Revision Date:

11/12/01

Trade Names:

IRM« LIQUID Zinc Oxide Eugenol Intermediate Restorative Material NFPA

Health: 2

Flammability: 1
Reactivity: 0
Other: N.A.

Product Codes:

```
****************
SECTION 2 : Hazardous Ingredients/Identity Information
*****************
Chemical Name
Eugenol CAS#
99-53-0 Percent
> 99 %
OSHA PEL TWA: Not Applicable
ACGIH TLV TWA: Not Applicable
Chemical Name
Acetic Acid CAS#
64-19-7 Percent
< 1 %
OSHA PEL TWA: 10 ppm
ACGIH TLV TWA: 10 ppm
************
SECTION 3 : Physical And Chemical Characteristics
******************
Physical State/Appearance:
Liquid.
Color:
 Colorless or pale yellow
Odor:
 Odor is oil of cloves.
Vapor Pressure:
 0.1 mm Hg @ 20 deg C
Vapor Density:
Not Established
Boiling Point:
 254 deg C/489 deg F
Melting Point:
 -9 deg C/-16 deg F
Solubility:
 In water: Slightly Soluble
Specific Gravity:
 1.0 \, \text{g/cm}^3
Evaporation Point:
 Not Established
FlashPoint:
 Approximately 252 deg F
Upper Flammable Explosive Limit:
 Not Established
Lower Flammable Explosive Limit:
 Not Established
***********************
SECTION 4 : Fire And Explosion Hazards
*******************
Flash Point:
 Approximately 252 deg F
Flash Point Method:
 Closed cup
Upper Flammable or Explosive Limit: Not Established
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Lower Flammable or Explosive Limit: Not Established Extinguishing Media:

Carbon dioxide, dry chemical or foam extinguishers.

Fire Fighting Instructions:

Fire fighters should wear full protective clothing including self-contained breathing apparatus. Cool containers exposed to flame with water.

Unusual Fire Hazards:

None, Material is not pyrophoric, does not react with water, not oxygen donor, material is shock stable.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 5 : Health Hazards

\*

Applies to all ingredients:

Route of Exposure: Inhalation: Yes

Skin: Yes

Ingestion: Possible

Potential Health Effects:

Acute: Liquid irritating to skin and eyes. Repeated contact may cause allergic dermatitis. Repeated daily oral doses of large amounts to rats caused liver damage. The effects in humans are unknown. Chronic Health Effects:

Liquid irritating to skin and eyes. Repeated contact may cause allergic dermatitis. Repeated daily oral doses of large amounts to rats caused liver damage. The effects in humans are unknown.

Carcinogenicity:

OSHA Designation: Regulated: No NTP Designation: Not listed

IARC Designation: Monographs: Not listed

Signs/Symptoms:

Product may irritate the eyes and skin.

Eye contact: Redness or irritation. Skin contact: Redness or irritation.

Eugenol:

Aggravation of Pre-Existing Conditions:

Persons with known sensitization to eugenol. Open sores or wounds of the skin.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 6 : Emergency And First Aid Procedures

\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Eye Contact:

In case of eye contact, flush with flowing water for 15 minutes, including under the eyelids and get medical attention. Skin Contact:

Flush with flowing water then wash area with mild soap and water. Ingestion:

Consult a physician.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 7 : Reactivity Data

\*\*\*\*\*\*\*\*\*\*\*\*\*

Chemical Stability: Stable Conditions to Avoid: (Stability): Excessive heat greater than 37 deg C/100 deg F. Incompatibilities with Other Materials: (Materials to avoid): Keep separated from strong bases, and strong oxidizing agents. Ferric chloride and potassium permanganate Hazardous Polymerization: Will not occur Conditions to avoid (polymerization): None. Hazardous Decomposition Products: Forms carbon monoxide and/or carbon dioxide upon burning. \*\*\*\*\*\*\*\*\*\*\*\*\* SECTION 8 : Precautions For Safe Handling \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* Spill Cleanup Measures: Absorb liquid with inert materials (sand, soda ash, vermiculite) and transfer to an appropriate closed container for disposal. Other Precautions: Eugenol darkens and thickens upon exposure to air. Observe normal warehouse handling procedures. Handling of this product should be by trained dental healthcare professionals only. Handling: Always close container immediately after use to prevent water absorption and contamination. Storage: Store at ambient temperature out of direct sunlight and heat. Do not store above 77 deg F (25 deg C). Do not expose to temperatures above 35 deg C Store in a dry area. Keep away from foodstuff and beverages. Hygiene Practices: Avoid eye and skin contact, inhalation and ingestion. Observe normal care when working with chemicals. Do not eat, drink or smoke when using. Waste Disposal: Dispose of in accordance with Federal, State and Local regulations. \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* SECTION 9 : Control Measures \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* Ventilation System: Local exhaust recommended. Hand Protection Description: Protective gloves: Rubber gloves. Eye/Face Protection: Close fitting protective goggles. Protective Clothing/Body Protection: Rubber apron. Respiratory Protection:

of vapors.

None required during normal use of this product. Avoid casual breathing

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********************
     Applies to all ingredients:
     TSCA 8(b): Inventory Status
      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.
     NFPA:
          Fire Hazard: 1
          Health: 2
          Reactivity: 0
          Specific Hazard: Not Applicable
     MSDS Preparation Date: 11/13/98
     MSDS Revision Date:
      11/12/01
     Abbreviations:
        NFPA - National Fire Protection Association
     N.A. - Not Applicable
     N.E. - Not Established
Copyright- 1996-2003 Actio Software Corporation. All Rights Reserved.
     Dentsply Caulk
           IRM POWDER
          Manufacturer MSDS Number: 510896NFPA
                1
                       0
     ***********************
     SECTION 1 : Chemical Product and Company Identification
     *******************
     MSDS Name: IRM Powder
     Manufacturer Name: Dentsply Caulk
     Address:
        38 West Clarke Avenue
     Milford DE 19963-0359
     Business Phone: (302) 422-4511
     For information in North America, call: (302) 422-4511
     For emergencies in the US, call CHEMTREC: 800-424-9300
     Manufacturer MSDS Creation Date:
        9/20/95
     Manufacturer MSDS Revision Date:
        11/13/98
     Trade Names:
       IRM« POWDER.
     NFPA
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Health: 1

Flammability: 0

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Reactivity: 0
   Other: N.A.
Product Codes:
  610007 , 610003.
*******************
SECTION 2 : Hazardous Ingredients/Identity Information
****************
Chemical Name
Zinc oxide
OSHA PEL TWA: 10 mg/mm3
ACGIH TLV TWA: 10 mg/mm3
Hazardous: Yes
***************
SECTION 3 : Physical And Chemical Characteristics
************
Physical State/Appearance:
Powder.
Color:
Whitish.
Odor:
Faint odor.
Vapor Pressure:
Not Applicable.
Vapor Density:
Not Applicable.
Boiling Point:
Not Applicable.
Melting Point:
Not Applicable.
Solubility:
 In water: Not Soluble.
Specific Gravity:
 5.7 \text{ g/cm}^3
Evaporation Point:
 Not Applicable.
FlashPoint:
 Not Applicable.
Upper Flammable Explosive Limit:
 Not Applicable.
Lower Flammable Explosive Limit:
 Not Applicable.
*******************
SECTION 4 : Fire And Explosion Hazards
********************
Fire:
 Flammability (explosive limits): Not Applicable.
Flash Point:
 Not Applicable.
Flash Point Method:
 Not Applicable.
Upper Flammable or Explosive Limit: Not Applicable.
Lower Flammable or Explosive Limit: Not Applicable.
Extinguishing Media:
 Water, carbon dioxide, or dry chemical extinguishers.
Fire Fighting Instructions:
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Avoid extinguishing methods; which may generate dust clouds. Water stream can disperse dust in air producing a fire hazard and possible explosion hazard if exposed to ignition source. Fire fighters should wear full protective clothing including a self-contained breathing apparatus. Unusual Fire Hazards:

Polymer dust is combustible. The explosive limits of the polymer particles suspended in air are approximately those of coal dust.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 5 : Health Hazards

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Zinc oxide:

Route of Exposure:

Inhalation: Yes.

Skin: No.

Ingestion: Possible.

Potential Health Effects:

Acute: It is not known to cause significant health problems. It is considered an inert or nuisance dust. Avoid inhalation of dust. Keep dust out of eyes to prevent possible irritation.

Chronic Health Effects:

It is not known to cause significant health problems. It is considered an inert or nuisance dust. Avoid inhalation of dust. Keep dust out of eyes to prevent possible irritation. Carcinogenicity:

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.

OSHA Designation: Regulated: No.

NTP Designation: Not listed.

IARC Designation: Monographs: Not listed.

Signs/Symptoms:

Product may irritate the eyes and skin.

Eye contact: Redness or irritation.

Skin contact: Redness or irritation.
Aggravation of Pre-Existing Conditions:
Open sores or wounds of the skin.

Eye Contact:

In case of eye contact, flush with flowing water for 15 minutes, including under the eyelids and get medical attention. Skin Contact:

Flush with flowing water then wash area with mild soap and water. Inhalation:

Remove to fresh air.

Ingestion:

Rinse mouth with water. Consult a physician if amount was large.

\*\*\*\*\*\*\*\*\*\*\*\*

SECTION 7 : Reactivity Data

\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Chemical Stability: Stable. Conditions to Avoid: (Stability): Excessive heat, greater than 50 deg C/122 deg F. Incompatibilities with Other Materials: (Materials to avoid): Not Applicable. Hazardous Polymerization: Will not occur. Conditions to avoid (polymerization): None. Hazardous Decomposition Products: From the polymer - methylmethacrylate and carbon monoxide. \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\* SECTION 8 : Precautions For Safe Handling \* Spill Cleanup Measures: As with any nuisance dust, avoid excessive dusting. Sweep up spilled powder to avoid slipping hazard and place in an appropriately marked container. keep airborne particulates to a minimum when cleaning up spills. Other Precautions: Observe normal warehouse handling procedures. Storage: Store in a cool, dry place away from food and beverages. Keep container closed to prevent water absorption and contamination. Work Practices: Observe normal care when working with chemicals. Hygiene Practices: Observe normal care when working with chemicals. Waste Disposal: Dispose of in accordance with Federal, State and Local regulations. \* SECTION 9 : Control Measures \* Ventilation System: Local exhaust recommended. Hand Protection Description: Protective gloves: Rubber gloves. Eye/Face Protection: Safety glasses. Protective Clothing/Body Protection: Rubber apron. Respiratory Protection: None required during normal use of this product. Local ventilation or approved nuisance dust mask, if in large quantities. \* SECTION 10 : Other Information \*

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Zinc oxide:

TSCA 8(b): Inventory Status

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.

#### NFPA:

Fire Hazard: 0 Health: 1 Reactivity: 0

Specific Hazard: Not Applicable.

MSDS Preparation Date: 9/20/95

MSDS Revision Date:

11/13/98

Abbreviations:

NFPA - National Fire Protection Association.

N.A. - Not Applicable. N.E. - Not Established.

510896 (R-11/98)

# DENTSPLY/International DENTSPLY/Caulk Safety Data Sheet

510896

#### 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	$10 \text{ mg/M}^3$	> 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 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 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

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

## 6. Accidental Release Measures

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

## 7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

## 8. Exposure Control / Personal Protection









Individual Protection	Personal Protective Equipment for Normal Use	Personal Protective Equipment for
Measures		Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required	Not Applicable
Body Protection Protective work clothing		Not Applicable
Occupational Exposure 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	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

### 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong acids, strong oxidizing agents.		
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 Ov	erview: Material may be mildly irritat	ing to eyes.			
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)
Eye	Material may cause slight	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.	
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 = 0, Reactivity = 1

## 12. Ecological Information

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



Hazardous to aquatic life

## 13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

**14.Transport Information** 

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

### 15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity:</u> This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

<u>Section 313 Toxic Chemicals</u>: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPO): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

<u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

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

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

European Community Labeling: Not a dangerous preparation.

<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.

<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u>: This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

#### 16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

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	$10 \text{ mg/M}^3$	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

### 3. Hazard Identification

Emergenc	Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.						
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health			
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)		
Eye	Material may cause slight	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.						
	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 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.		

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 Physicians (7	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:	Air Not Applicable	Autoignition Temperature: Not Applicable.	Other: Not Applicable
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Inte	11	Flammability Classification:	Applicable
Solids) Not Applicable	Applicable		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 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 Limi	Occupational Exposure Limits: 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>	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	
Other: Not Applicable		

## 10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong oxidizing agents.			
Hazardous Products Produced During Decomposition: Forms carl	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

	11.1 Oxicological information				
Toxicity Data,	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 Ov	erview: Material may be mildly irritat	ing to eyes.			
Routes of		Single, Repeated, or	Severity (Mild,	Acute and Chronic Health	
Exposure	Signs and Symptoms	Lifetime Exposure	Moderate, Severe)	Effect(s)	Target Organ(s)
Eye	Material may cause slight	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.	

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 (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	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

### **15.Regulatory Information**

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity:</u> This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

<u>Section 313 Toxic Chemicals:</u> This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPQ): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

<u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

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

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

European Community Labeling: Not a dangerous preparation.

European Community Labeling: 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

510896

#### 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	$10 \text{ mg/M}^3$	> 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 Env	Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					

### 4. First Aid Measures

Routes of	Routes of First Aid Instructions		Delayed Effects		
Exposure	Exposure				
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

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air		Autoignition Temperature: Not	Other: Not
	LEL: Not Applicable UEL:	Not Applicable	Applicable.	Applicable
Flame Propagation or Burning Rate (for	Properties Contributing to Fire Into	ensity: Not	Flammability Classification:	
Solids) Not Applicable	Applicable		Not Applicable	
Extinguishing Media: CO <sub>2</sub> , powder, or water spr	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	Individual 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	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	Autoignition Temperature: Not Applicable
	LEL: Not Applicable UEL: Not Applicable	
Other: Not Applicable		

### 10. Stability and Reactivity Data

	Incompatibility (Materials to Avoid): Strong acids, strong oxidizing agents.		
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,	Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:					
Not Applicable	Not Applicable					
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	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.		
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 = 0, Reactivity = 1

## 12. Ecological Information

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



Hazardous to aquatic life

## 13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations

Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

**14.Transport Information** 

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment	DOT Hazard Class: Not Applicable	UN Number: Not Applicable
method change product classification? No		

### 15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.

U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity:</u> This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations

<u>Section 313 Toxic Chemicals</u>: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

Section 302 Extremely Hazardous Substances (TPO): None

EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.

<u>U.S. State Regulations California Proposition 65:</u> This product does not contain any chemicals, which are on the California Proposition 65 list.

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

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

European Community Labeling: Not a dangerous preparation.

<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.

<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u>: This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

#### 16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.