

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071738020

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

071737402 071738608 071891258 078289800 078291200 078291900

**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).**

071737444

**DENTSPLY/International  
DENTSPLY/Caulk  
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>04/15/11</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a> <a href="http://www.dentsply.com">http://www.dentsply.com</a></b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Information Telephone Number <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>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</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	99-53-0	10 mg/M <sup>3</sup>	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

**3. Hazard Identification**

<b>Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.</b>					
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
<b>Medical Conditions Aggravated by Exposure</b> Open sores and wounds of the skin.					
<b>Carcinogenicity</b> 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.					
<b>Potential Environmental Effects</b> Do not allow to enter sewers/ surface or ground water.					

**4. First Aid Measures**

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult 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>	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 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

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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.

### 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 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: CERCLA 103 Reportable Quantity: 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**

**510896****1. Identification**

Product Name IRM <sup>®</sup> Powder Zinc Oxide Eugenol Intermediate Restorative Material	SDS Code Number 510896
Substance Identity IRM <sup>®</sup> Powder Zinc Oxide Eugenol Intermediate Restorative Material	Date of Last Revision 04/15/11
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a> <a href="http://www.dentsply.com">http://www.dentsply.com</a>
Grades or Minor Variant Identities Not Applicable	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Temporary Restorative	Emergency Telephone Number (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 <sup>3</sup>	> than 75

**3. Hazard Identification**

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 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

### 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

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: CERCLA 103 Reportable Quantity: 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: 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.

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.

# MATERIAL SAFETY DATA SHEET

## SECTION I - Product/Company Identification

1.1 Product Trade Name: **IRM<sup>®</sup> POWDER Zinc Oxide Eugenol**  
**Intermediate Restorative Material**  
1.2 Part (Item) Number: 610003, 610007 All Package Configurations  
1.3 Division Name: DENTSPLY Caulk  
1.4 Address: 38 West Clarke Avenue  
City State Zip: Milford DE 19963-0359  
Internet Address: <http://www.caulk.com>  
1.5 Emergency Telephone Number: (800) 424-9300 (Chemtrec)  
1.6 Telephone Number for Information: (302) 422-4511 (8:00 AM - 4:30 PM Eastern Time)  
1.7 Date Prepared: 11/13/98 Date Revised: 11/12/01

## SECTION II - Hazardous Ingredients/Identity Information

Hazardous Components	OSHA PEL	ACGIH TLV	CAS #	Percent
Zinc oxide	10 mg/mm <sup>3</sup>	10 mg/mm <sup>3</sup>	1314-13-2	Greater than 75%

## SECTION III - Physical/Chemical Characteristics

3.1 Boiling point:	N. A.	3.6 Specific Gravity:	5.7 g/cm <sup>3</sup>
3.2 Vapor pressure:	N. A.	3.7 Melting Point:	N. A.
3.3 Vapor density:	N. A.	3.8 Evaporation rate:	N. A.
3.4 Solubility in water:	Not Soluble		
3.5 Appearance and odor:	Whitish powder with faint odor.		

## SECTION IV - Fire and Explosion Hazard Data

4.1 Flash point (method used): N. A.  
4.2 Flammability (explosive limits): LEL: N. A. UEL: N. A.  
4.3 Extinguishing media: Water, carbon dioxide, or dry chemical extinguishers.  
4.4 Special fire fighting procedures: 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 self-contained breathing apparatus.  
4.5 Unusual fire and explosion hazards: Polymer dust is combustible. The explosive limits of the polymer particles suspended in air are approximately those of coal dust.

## SECTION V - Reactivity Data

5.1 Stability:	Unstable:	Stable: X
5.2 Conditions to avoid (stability):	Excessive heat, greater than 50°C/122°F.	
5.3 Incompatibility (materials to avoid):	N. A.	
5.4 Hazardous decomposition or byproducts:	From the polymer - methymethacrylate and carbon monoxide.	
5.5 Hazardous polymerization:	May occur:	Will not occur: X
5.6 Conditions to avoid (polymerization):	None.	



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## SECTION VI - Health Hazard Data

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- 6.1 Route(s) of entry: Inhalation?: Yes Skin?: No Ingestion?: Possible
- 6.2 Health hazards (acute and chronic): 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.
- 6.3 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.
- 6.4 Signs and symptoms of exposure: Product may irritate the eyes and skin. Eye contact: Redness or irritation.  
Skin contact: Redness or irritation.
- 6.5 Medical conditions generally aggravated by exposure: Open sores or wounds of the skin.
- 6.6 Emergency first aid procedures: Inhalation: Remove to fresh air. Eyes: In case of eye contact, flush with flowing water for 15 minutes, including under the eyelids and get medical attention. Skin: Flush with flowing water then wash area with mild soap and water. Ingestion: Rinse mouth with water. Consult a physician if amount was large.
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## SECTION VII - Precautions for Safe Handling and Use

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- 7.1 Steps to be taken in case material is released or spilled: 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.
- 7.2 Waste disposal methods: Dispose of in accordance with Federal, State and Local regulations.
- 7.3 Precautions to be taken in handling and storage: Always close container immediately after use to prevent water absorption and contamination. Store at ambient temperature out of direct sunlight and heat. Store in a dry area. Keep away from foodstuff and beverages.
- 7.4 Other precautions: Observe normal warehouse handling procedures. Handling of this product should be by trained dental healthcare professionals only.
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## SECTION VIII - Control Measures / Personal Protection

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- 8.1 Respiratory protection: None required during normal use of this product. Local ventilation or approved nuisance dust mask, if in large quantities.
- 8.2 Ventilation: Local exhaust recommended.
- 8.3 Protective gloves: Rubber gloves.
- 8.4 Eye protection: Safety glasses.
- 8.5 Other protective clothing or equipment: Rubber apron.
- 8.6 Work/Hygienic practices: Observe normal care when working with chemicals. Handling of this product should be by trained dental healthcare professionals only. Avoid eye and skin contact, inhalation and ingestion. Do not eat, drink or smoke when using.
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NFPA HAZARD CLASSIFICATIONS	
Health	1
Flammability	0
Reactivity	0
Specific Hazard	N A

NFPA - National Fire Protection Association  
N.A. - Not Applicable  
N.E. - Not Established

510896 (R-11/12/01)

**DENTSPLY/International  
DENTSPLY/Caulk  
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>04/15/11</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a> <a href="http://www.dentsply.com">http://www.dentsply.com</a></b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Information Telephone Number <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>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</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	99-53-0	10 mg/M <sup>3</sup>	> than 98
Acetic Acid	64-19-7	10 PPM	< than 2

**3. Hazard Identification**

<b>Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.</b>					
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 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>	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 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.

## 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 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: CERCLA 103 Reportable Quantity: 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**

**510896**

**1. Identification**

Product Name <b>IRM<sup>®</sup> Powder Zinc Oxide Eugenol Intermediate Restorative Material</b>	SDS Code Number <b>510896</b>
Substance Identity <b>IRM<sup>®</sup> Powder Zinc Oxide Eugenol Intermediate Restorative Material</b>	Date of Last Revision <b>04/15/11</b>
Manufacturer: <b>DENTSPLY Caulk</b>	Address <b>38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.caulk.com">http://www.caulk.com</a> <a href="http://www.dentsply.com">http://www.dentsply.com</a></b>
Grades or Minor Variant Identities <b>Not Applicable</b>	Information Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</b>
Product Use (for Canada) <b>Temporary Restorative</b>	Emergency Telephone Number <b>(302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)</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	%
Zinc oxide	1314-13-2	10 mg/M <sup>3</sup>	> than 75

**3. Hazard Identification**

<b>Emergency Overview: Material may be irritating to eyes. No significant hazards for emergency responses are known.</b>					
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
<b>Medical Conditions Aggravated by Exposure</b> Open sores and wounds of the skin.					
<b>Carcinogenicity</b> 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.					
<b>Potential Environmental Effects</b> Do not allow to enter sewers/ surface or ground water.					

**4. First Aid Measures**

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly.	Not Applicable	Not Applicable

Inhalation	Supply fresh air, consult physician if symptoms persist.	Not Applicable	Not Applicable
Ingestion	Rinse mouth out and then drink plenty of water. If symptoms persist consult physician.	Not Applicable	Not Applicable
Other	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

## 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

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: CERCLA 103 Reportable Quantity: 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: 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.

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.