DENTSPLY/International
DENTSPLY/Caulk
Safety Data Sheet **510896**

1. Identification

Product Name IRM® Powder Zinc Oxide Eugenol Intermediate Restorative Material	SDS Code Number 510896
Substance Identity IRM® Powder Zinc Oxide Eugenol Intermediate Restorative Material	Date of Last Revision 02/21/14
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com
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^3	> 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_2, powder, or water spray.	Extinguishing Media to Avoid: Water with full jet.		
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: During a fire, formation of toxic and/or irritating compounds may be present.			

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^3	Solubility in Water: Partially soluble.	pH: Not Applicable
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air 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: ☐May Occur ☒May Not Occur	Conditions to Avoid: None known
Stability? ☒Stable ☐Unstable	Conditions to Avoid: None known

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Not Applicable					
Emergency Overview: Material may be mildly irritating to eyes.					
Routes of 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. R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

Danger
Hazardous to aquatic life

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

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: R50/53Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste.
European Inventory of New and Existing Chemicals Substances (EINECS): This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship. The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.