

# iSmile Dental Products Safety Data Sheet

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## 1. PRODUCT IDENTIFICATION

**Trade Name (as labeled):** Dental Points - Gutta Percha  
**Chemical Name/Classification:** Gutta Percha Points  
**Product Identifier (Part/Item Number):** Gutta Percha Points  
**U.N. Number:** 3077  
**U.N. Dangerous Goods Classification:** 9 (R36, R50/53, S3, S26, S60, S61)  
**Recommended Use:** Root Canal Filler  
**Restrictions on Use:** For Dental use only. This product should not be used in patients allergic to latex products.  
**Distributed by:** iSmile Dental Products  
**Distributor Address:** 4201 Sierra Point Drive, Suite 102, Sacramento, CA 95834  
**Distributor Telephone Number:** 888-745-4734 (Product Information)  
**Emergency Contact Telephone Number:** Chemtrec (800)-262-8200  
**Email address:** [Chemtrec@chemtrec.com](mailto:Chemtrec@chemtrec.com)

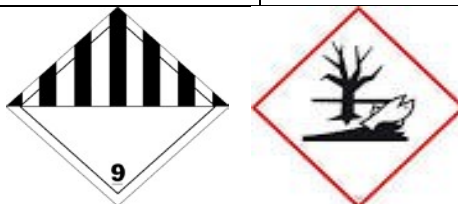
## 2. HAZARD(S) IDENTIFICATION

**Hazard/Danger Classification:**

Health	Environmental	Physical
R36	9, R50/53	None

**Associated Hazards:**

Hazard Statements	Precautionary Statements
S60, S61	S3, S26



EU Classification: I

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EU Risk (R) and Safety (S) Phrases: R 36, S3, S26

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

## 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Gutta Percha	9000-32-2 232-537-3	Gutta Percha	R36,S2,S26	25%
Zinc Oxide	1314-13-2 215-222-5	Zinc Oxide	R50, S60, S61	62.5%
Barium Sulfate	7727-43-7 231-784-4	Barium Sulfate	NA	12%
Coloring Agent			NA	.5%

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.





## 4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Solid material may cause irritation or cornea injury due to mechanical action. Contact physician for treatment.
Skin	Non-irritating to the skin.
Inhalation	NA
Ingestion	Product is to be handled by professional dentist only. Aspiration is avoided by the use of rubber dam on the patient during application.
Most important symptoms of exposure	None
Other	This product should not be used in patients allergic to latex products.
<b>Note to Physicians (Treatment, Testing, and Monitoring)</b>	
Treat Symptomatically	

## 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Water, foam CO2 & dry chemical
<b>Fire Fighting Procedures:</b>	Protective clothing and self-contained breathing apparatus in closed space
<b>Specific Hazards Arising from the Chemical:</b>	None
<b>Precautions for Fire Fighters:</b>	None expected

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Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, PPE and Emergency Procedures:** Safety Glasses/Goggles

**Environmental Precautions:** None required

**Methods and Materials for Containment and Clean-up:** Collect into a suitable container and discard. Dispose of in accordance with federal, state and local regulations.

**Recommended Personal Protective Equipment for Containment and Clean-up:**

**EYES/FACE**



## 7. HANDLING AND STORAGE


**Precautions for Safe Handling:** Practice reasonable care. Do not autoclave. Sterilize in conventional manner with cold disinfectants, or alcohol. Avoid prolonged exposure to natural light and above 37°C.

**Conditions for Safe Storage:** Store in a dry dark environment at temperature not above 700F. Preferably stored in refrigerator. Keep away from daylight or direct sunlight. Store away from oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Occupational Exposure Limits:** None determined

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<b>Biological Exposure Limits:</b> None determined
<b>Appropriate Engineering Controls:</b> None Determined
<b>Individual Protection Measures (PPE)</b> <b>Specific Eye/face Protection:</b> Safety Glasses/Goggles <b>Specific Skin Protection:</b> None required <b>Specific Respiratory Protection:</b> None required <b>Specific Thermal Hazards:</b> None required
<b>Recommended Personal Protective Equipment</b>
EYES/FACE

<b>Environmental Exposure Controls:</b> None required
<b>General Hygiene Considerations and Work Practices:</b> None Required
<b>Protective Measures During Repair and Maintenance of Contaminated Equipment:</b> None Required

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	A solid rubber like material at room temperature orange/pink in color	<b>Explosive limits:</b>	NA
<b>Odor:</b>	Gutta Percha latex has a slight odor of its own. The compound has no perceptible odor.	<b>Vapor pressure:</b>	NA
<b>Odor threshold:</b>	NA	<b>Vapor density:</b>	NA
<b>pH:</b>	NA	<b>Relative density:</b>	NA
<b>Melting/freezing point:</b>	Softens at 80°C	<b>Solubility:</b>	Water - No Ether - Yes
<b>Initial boiling point and range:</b>	NA	<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Flash point:</b>	NA	<b>Auto-ignition temperature:</b>	NA
<b>Evaporation rate:</b>	NA	<b>Decomposition temperature:</b>	NA

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<b>Flammability:</b>	NA	<b>Viscosity:</b>	NA
<b>Explosive Properties:</b>	NA	<b>Oxidizing Properties:</b>	NA

## 10. STABILITY AND REACTIVITY

**Reactivity:** This is a stable compound that will not degrade to unstable products or hazardous materials.

**Chemical Stability:** Stable

**Possibility of Hazardous Reactions:** Will not occur

**Conditions to Avoid:** Natural light, excessive heat and humidity

**Incompatible materials:** Strong Oxidants

**Hazardous Decomposition Products:** Carbon Monoxide, Carbon Dioxide, Hydrocarbons, and Zinc fumes

## 11. TOXICOLOGICAL INFORMATION

**Signs and Symptoms of Overexposure:** None

**Emergency Overview:** NA

Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
<b>Eye:</b>	None	None	None	None	None	None	None
<b>Skin:</b>	None	None	None	None	None	None	None
<b>Inhalation:</b>	None	None	None	None	None	None	None
<b>Ingestion:</b>	None	None	None	None	None	None	None
<b>Other:</b>	None	None	None	None	None	None	None

**Medical Conditions Aggravated by Exposure:** None

**Carcinogenicity:** None

## 12. ECOLOGICAL INFORMATION

**Toxicity:** Gutta Percha compound passes the Special Waste Acceptance Protocol. Validation made by independent testing laboratory according to EPA methods 200.7 and 1311.

**Persistence and Degradability:** None

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<b>Bio-accumulative Potential:</b> None
<b>Mobility in Soil:</b> None determined
<b>Other Adverse Effects:</b> None
<b>Results of PBT/vPvB Assessment:</b> None

## 13. DISPOSAL CONSIDERATIONS

<b>Regulations:</b> Product is not a hazardous waste. Landfill or incinerate in accordance with federal, state and local requirements. See #12.
<b>Properties (Physical/Chemical) Affecting Disposal:</b> None
<b>Waste Treatment Recommendations:</b> None

## 14. TRANSPORT INFORMATION

<b>UN Identification Number:</b> 3077
<b>UN Proper Shipping Name:</b> Not Regulated
<b>Transport hazard class(es):</b> Not Regulated
<b>Packing Group:</b> III
<b>Special precautions for user:</b> NA

## 15. REGULATORY INFORMATION

**U.S. Federal Regulations**

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** Not Listed

**Toxic Substances Control Act (TSCA):** International ingredients of this product are listed

**Clean Water Act (CWA):** Listed – Zinc Oxide

**Clean Air Act (CAA):** None

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:** None

**SARA Section 311/312 (40 CFR 370) Hazard Categories:** Yes (Acute)

<b>Immediate Hazard:</b>	Irritant Toxic to Aquatic Organisms	<b>Pressure Hazard:</b>	None
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<b>Delayed Hazard:</b>	None	<b>Reactivity Hazard:</b>	None
<b>Fire Hazard:</b>	None		

**This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):**

Components	C.A.S. #	WT %
Zinc Oxide	1314-13-2	62.5%

## State Regulations

**California:** This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None	None	None

## International Regulations

**Canadian Environmental Protection Act:** Domestic substance list (DSL) - listed

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Not Controlled

**European Inventory of Existing Chemicals (EINECS):** 215-222-5

## 16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Zinc Oxide) UN 3077, Class 9, PG III, Classification Code M7

R36 Irritating to eyes

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S3 Keep in a cool place

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S60 This material and its container must be disposed of as hazardous waste

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets

Date of SDS Preparation/Revision: 08/11/2014

Data Sources: Supplier

Annex IV of European Union Directive 67/548/EEC and Directive 2001/59/EC

National Institute for Occupational Safety (NIOSH)

US Occupational Safety and Health Administration (OSHA)