

Roydent 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: Roydent Dental Products
Distributor Address: 608 Rolling Hills Dr., Johnson City, TN 37604
Distributor Telephone Number: 800-992-7767 (Product Information)
Emergency Contact Telephone Number: Chemtrec (800) -262-8200
Email address: Chemtrec@chemtrec.com

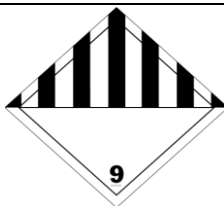
2. HAZARD(S) IDENTIFICATION

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. |
| Note to Physicians (Treatment, Testing, and Monitoring) | |
| Treat Symptomatically | |

5. FIRE-FIGHTING MEASURES

| | |
|------------------------------------------------|----------------------------------------------------------------------------|
| Suitable Extinguishing Media: | Water, foam CO2 & dry chemical |
| Fire Fighting Procedures: | Protective clothing and self-contained breathing apparatus in closed space |
| Specific Hazards Arising from the Chemical: | None |
| Precautions for Fire Fighters: | 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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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Biological Exposure Limits: None determined |
| Appropriate Engineering Controls: None Determined |
| Individual Protection Measures (PPE) Specific Eye/face Protection: Safety Glasses/Goggles Specific Skin Protection: None required Specific Respiratory Protection: None required Specific Thermal Hazards: None required |
| Recommended Personal Protective Equipment |
| EYES/FACE |
|  |
| Environmental Exposure Controls: None required |
| General Hygiene Considerations and Work Practices: None Required |
| Protective Measures During Repair and Maintenance of Contaminated Equipment: None Required |

9. PHYSICAL AND CHEMICAL PROPERTIES

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

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|------------------------------|----|------------------------------|----|
| Flammability: | NA | Viscosity: | NA |
| Explosive Properties: | NA | Oxidizing Properties: | 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) |
|---------------------------|--------------------|----------------------------------------|-----------------------------------|------------------------------------|-----------------|-----------------------------------|-----------------------------------|
| Eye: | None | None | None | None | None | None | None |
| Skin: | None | None | None | None | None | None | None |
| Inhalation: | None | None | None | None | None | None | None |
| Ingestion: | None | None | None | None | None | None | None |
| Other: | 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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Bio-accumulative Potential: None

Mobility in Soil: None determined

Other Adverse Effects: None

Results of PBT/vPvB Assessment: None

13. DISPOSAL CONSIDERATIONS

Regulations: Product is not a hazardous waste. Landfill or incinerate in accordance with federal, state and local requirements. See #12.

Properties (Physical/Chemical) Affecting Disposal: None

Waste Treatment Recommendations: None

14. TRANSPORT INFORMATION

UN Identification Number: 3077

UN Proper Shipping Name: Not Regulated

Transport hazard class(es): Not Regulated

Packing Group: III

Special precautions for user: 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)

| | | | |
|--------------------------|----------------------------------------|-------------------------|------|
| Immediate Hazard: | Irritant Toxic to Aquatic Organisms | Pressure Hazard: | None |
|--------------------------|----------------------------------------|-------------------------|------|

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|------------------------|------|---------------------------|------|
| Delayed Hazard: | None | Reactivity Hazard: | None |
| Fire Hazard: | 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 chemical(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)