

ROYDENT	MATERIAL SAFETY DATA SHEET	Revision: F Valid From: 06/01/01 Control: 001
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1. PRODUCT NAME AND MANUFACTURER:

- 1.1 Dental Points - Gutta Percha
- 1.2 United Dental Manufacturers, Inc.
PO Box 700874
Tulsa, OK 74170

2. INGREDIENTS:

- 2.1 Natural Gutta Percha Latex
Zinc Oxide
Barium Sulfate
Anti-Oxidant
Wax
Pigment

3. HAZARDOUS IDENTIFICATION:

3.1 Emergency Overview:

These products are solid rubber like tapered cones. A spillage in large amounts could create a slipping hazard.

3.2 Potential Health Effects:

- Eye: Product may cause irritation of injury due to mechanical action.
- Skin: Not likely to cause skin irritation.
- Ingestion: Not toxic (see 4.3).
- Inhalation: Inhalation unlikely due to physical form.
- Carcinogenicity: Not known to cause cancer in humans or animals.

4. FIRST AID MEASURES:

- 4.1 Eye Contact - Solid material may cause irritation or cornea injury due to mechanical action.
Contact physician for treatment.
- 4.2 Skin contact - Non irritating to the skin.
- 4.3 Ingestion - Product is to be handed by professional dentist only.
Aspiration is avoided by the use of rubber dam on the patient during application.

5. FIRE FIGHTING MEASURES:

- 5.1 Extinguishing Media - Water, foam CO₂ & dry chemical.
- 5.2 Explosion Hazard - None.
- 5.3 Fire Fighting Equipment - Protective clothing and self-contained breath apparatus in closed space.

6. ACCIDENTAL RELEASE MEASURES:

- 6.1 Spills and Leaks - Collect into a suitable container and discard.
- 6.2 Waste Disposal - Dispose of in accordance with federal, state and local regulations.

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7. HANDLING AND STORAGE:

- 7.1 Exposure Guideline: None established
- 7.2 Ventilation: N/A
- 7.3 Respiratory Protection: None should be needed
- 7.4 Skin Protection: No special protection shall be needed
- 7.5 Eye Protection: N/A
- 7.6 Additional Information: Special precautions to be taken in handling: practice reasonable care. Do not autoclave. Sterilize in conventional manner with cold disinfectants, or alcohol.
- 7.7 Storage: Store in a dry dark environment at temperature not above 70°F. Preferably stored in refrigerator. Keep away from daylight or direct sunlight.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION:

- 8.1 Exposure Controls - None established or required.
- 8.2 Personal Protection - No special requirements for respiratory, hand, eye or skin protection are necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES:

- 9.1 Appearance - A solid rubber like material at room temperature orange/pink in color.
- 9.2 Odor - Gutta Percha latex has a slight odor of it's own. The compound has no perceptible odor.
- 9.3 Boiling Point - N/A
- 9.4 Vapor Pressure - N/A
- 9.5 Solubility - Water - No
Ether - Yes

10. STABILITY AND REACTIVITY:

- 10.1 This is a stable compound that will not degrade to unstable products or hazardous materials.

11. TOXICOLOGICAL INFORMATION:

- 11.1 Toxicity Data - Toxicity data is either unknown or not available for this material, however the extended use of Gutta Percha as an endodontic filling material is evidence of its successful clinical application in humans. Gutta Percha blends have been in use since before 1900.
- 11.2 Toxicological Findings - An evaluation of toxicological data on this is currently unavailable. See section 3 of the MSDS for an overview of known or anticipated health effects.

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12. **ECOLOGICAL INFORMATION:**

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

13. **DISPOSAL CONSIDERATIONS:**

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

14. **TRANSPORT INFORMATION:**

14.1 DOT Hazard Class - Not regulated
14.2 Proper Shipping Name - Not regulated

15. **REGULATORY INFORMATION:**

15.1 These products are manufactured to standards under ISO 6877 International standards - dental root canal obturating points and ANSI/ADA Specification #78 Endodontic Obturating points. Product is registered with the U.S. Department of Health, Food and Drug Administration and meets the GMP of 21CFR820.

16. **OTHER INFORMATION:**

16.1 This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of United Dental Manufactures, Inc. The data on this sheet relates only to the specific material designated herein. United Dental Manufacturers, Inc. assumes no legal responsibility for use or reliance upon this data.

16.2 This product should not be used in patients allergic to latex products.