SAFETY DATA SHEET
Traxodont® Hemodent® Paste Retraction System

1. Chemical Product and Company Identification
   Product Name: Traxodont® Hemodent® Paste Retraction System
   
   Premier Dental Products Company
   1710 Romano Drive
   Plymouth Meeting, PA 19462
   Phone: 610-239-6000 Fax: 610-239-6171
   Emergency Phone: 610-239-6000

   Indications:
   Traxodont® has been specifically formulated to provide gingival retraction and hemostasis. It is intended for use prior to taking an impression, cementation, cavity preparation or wherever hemostasis and retraction is required.

   Contraindications:
   • Do not use on persons with known allergy to aluminum chloride
   • Do not use in patients with significant periodontal disease or furcation involvement.

   Precautions:
   • Do not insert canula dispensing tip into the sulcus.
   • Be sure all paste is removed before taking impression to avoid inhibition of polymerization of impression material.

2. Hazards Identification
   Acute Health Hazards: May cause eye, respiratory and skin irritation in high concentration.
   Chronic Health Hazards: Material is not known to cause significant health problems
   Signs and Symptoms of Exposure: High concentrations can cause eye and respiratory irritation. Prolonged skin exposure can cause dryness
   Primary routes of exposure: Inhalation, skin contact, eye contact.
   Carcinogenicity: NTP - no, OSHA - no, IARC – no.
   Hazard symbol: ❗

3. Composition / Information on Hazardous Ingredients

<table>
<thead>
<tr>
<th>Hazardous Ingredients</th>
<th>CAS #</th>
<th>Hazard Identification &amp; Risk Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum Chloride Hexahydrate</td>
<td>7784-13-6</td>
<td>Irritant, R36/38</td>
</tr>
<tr>
<td>Fumed Silica</td>
<td>7631-86-9</td>
<td>R36/37/38</td>
</tr>
<tr>
<td>Potassium Sorbate</td>
<td>590-00-1</td>
<td>R36/38</td>
</tr>
<tr>
<td>Potassium Nitrate</td>
<td>7757-79-1</td>
<td>R8</td>
</tr>
<tr>
<td>Yellow Pigment FD&amp;C Yellow No.5</td>
<td>1934-21-0</td>
<td>R36</td>
</tr>
</tbody>
</table>

   ✓ Additional information: For the wording of the listed risk phrases refer to section 16.

4. First Aid Measures
   In case of inhalation: If irritation occurs, take victim to open air. Get medical attention.
   In case of skin contact: Wash with soap and water.
   In case of eye contact: Flush with large quantities of water for 15 minutes. Consult a physician.
   In case of ingestion: Wash out of mouth with water. Consult a physician if a substantial amount has been ingested. Do not induce vomiting.

5. Fire-Fighting Measures
   Flash point: Non-flammable
   Extinguishing Media: Carbon dioxide, water spray, dry chemical
   Unusual Fire and Explosion Hazards: Upon combustion, irritating gases may form.
6. Accidental Release Measures
   Personal Precautions: Prevent skin / eye contact
   Environmental Precautions: Avoid ground water contamination

7. Handling and Storage
   Handling: No special measures necessary if handled according to instruction
   Storage: Keep container tightly closed when not in use. Store at room temperature. Keep material in original packaging. Avoid unnecessary exposure to the product.

8. Exposure Controls / Personal Protection
   Exposure Controls: Use only in well-ventilated areas
   Eye Protection: Wear protective eyewear
   Hand and Skin Protection: Avoid unnecessary skin contact. Wear latex gloves when handling
   Hygiene Measures: Remove spilled material from skin and clothing. Do not eat or drink when handling this material

9. Physical and Chemical Properties
   Appearance: Light yellow paste
   Odor: Odorless
   Boiling Point: N/A
   Evaporation Rate (Water = 1): N/A
   Vapor Density (Air = 1): N/A
   Solubility in Water: Miscible
   Viscosity: Viscous

10. Stability and Reactivity
    Stability: This material is stable.
    Hazardous Reactions: None if handled according to directions
    Conditions to Avoid: Heat
    Incompatibility: Strong caustics, metal, acids

11. Toxicological Information
    Acute oral toxicity: Aluminum Chloride Hexahydrate
        IPR MUS LD50 940 mg/kg
        IPR RAT LD50 728 mg/kg
        ORL MUS LD50 1990 mg/kg
        ORL RAT LD50 3311 mg/kg
    Irritation of Eyes: Irritates the eyes
    Irritation of Skin: May irritates the skin
    Allergic Effects: May cause allergic reaction on contact with skin.
    Other: If swallowed, may cause sore throat and burns of the mouth and throat. Prolonged exposure may cause burns to the respiratory tract, contact with the soft tissue may cause burns.

12. Ecological Information
    Hazardous Ingredients: Aluminum Chloride Hexahydrate
        DAPHINA 48H EC50 27.3mg/l
        FISH 96H LC50 27.1 mg/l
Mobility: Readily absorbed into soil
Persistence and Degradability: Biodegradable
Bioaccumulative Potential: No bioaccumulation potential
Other Adverse Effects: Negligible ecotoxicity.
Use according to good working practices, avoid release of the product into the environment.

13. Disposal Considerations
May be disposed of in landfill or incinerator in accordance with local, state and federal regulations

14. Transport Information
14.1 Transport at land
ADR: 
RID:
UN Number: Kemler Number: ----
Packing Group: Proper Shipping Name: 

14.2 Transport at sea
ADR: 
RID:
UN Number: IMDG:
EMS: MFAG: 
Packing Group: Proper Shipping Name: 

14.3 Air transport
ICAO / IATA-DGR: 
UN Number: 
Proper Shipping Name:
Subsidiary Risk: ----- Labels: 
Packing Group: 

U.S. DOT Shipping Name: Not Regulated
U.S. DOT Hazard Class: None U.N. /N.A.
Number: None
U.S. DOT Packing Group: None
Other: Not considered hazardous cargo

15. Regulatory Information
This product requires classification according to the criteria of EC.
The product is a medical device according to the EC-directive 93/42.
15.1 UN Number: 2581
15.2 National regulations: ----
15.3 EU number: 231-208-1
15.4 Hazard symbols: 

15.5 Hazard designation:
Irritant: contains Aluminum Chloride Hexahydrate solution in water.
15.6 Risk phrases: R – 34, 36/37/38
Causes burn. Irritating to eyes, respiratory system and skin
15.7 Safety phrases: S – ½, 26, 37/39, 45
  ½ - Keep locked out of the reach of children
  26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
  37/39 – Wear suitable gloves and eye / face protection.
  45 – In case of accident or if you feel unwell, seek medical advice immediately. (show the label where possible)

U.S.-O.S.H.A. Status: This material is not hazardous under the criteria of the U.S Federal Hazard Communication Standard.

16. Other Information

Premier’s revision date: 07-28-14
Revision Number: 7

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall establish a legally valid contractual relationship.

Relevant R-phrases

  34 - Causes burns
  36 - Irritating to eyes
  37/38 - Irritating respiratory system and skin.

Material should be maintained in original containers. Empty containers should not be re-used.

ANSI/NFPA 704 Data

  Fire = 0
  Health = 1
  Reactivity = 0

Supplier date: 07-15-2014

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