

SAFETY DATA SHEET

Traxodent® Hemodent® Paste Retraction System

1. Chemical Product and Company Identification

Product Name: Traxodent® Hemodent® Paste Retraction System

Premier Dental Products Company

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Plymouth Meeting, PA 19462

Phone: 610-239-6000 Fax: 610-239-6171

Emergency Phone: 610-239-6000

Indications:

Traxodent® 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

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

✓ **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

Clean-Up Procedure: Wipe with damp paper towel. Discard properly.

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:

UN Number:

Packing Group:

Proper Shipping Name:

RID:

Kemler Number: ----

14.2 Transport at sea

ADNR:

UN Number:

EMS:

Packing Group:

Proper Shipping Name:

IMDG:

MFAG:

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: 11/25/2015

Revision Number: 8

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's number: 071514

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