SAFETY DATA SHEET
Traxodent® Hemodent® Paste Retraction System

1. Chemical Product and Company Identification
   Trade Name: Traxodent® 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:
   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
   Classification of the substance or mixture:

   !
   GHS07

   Skin Irrit. 2 H315 Causes skin irritation
   Eye Irrit. 2B H319 Causes eye irritation

   Label elements:
   GHS label elements
   The product is classified and labeled according to the Globally Harmonized System (GHS).

   Hazard pictograms:

   !
   GHS07

   Signal word: Warning

   Hazard-determining components of labeling:
   Aluminum Chloride Hexahydrate

   Hazard statements:
   H315+H319 Causes skin and eye irritation.

   Precautionary statements:
   P280   Wear protective gloves.
   P264   Wash thoroughly after handling.
   P305+P351+P338   If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
   P321   Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
   P332+P313   If skin irritation occurs: Get medical advice/attention.
   P337+P313   If eye irritation persists: Get medical advice/attention.
   P302+P352   IF ON SKIN: Wash with plenty of water.
   P362+P364   Take off contaminated clothing and wash it before reuse.
Unknown acute toxicity:
This value refers to knowledge of known, established toxicological or ecotoxicological values. 26% of the mixture consists of component(s) of unknown toxicity.

Classification system: NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

NFPA ratings (scale 0 - 4)

Health = 1
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 1
Fire = 0
Reactivity = 0

Hazard(s) not otherwise classified (HNOC): None known

3. Composition / Information on Hazardous Ingredients

Chemical characterization: Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

<table>
<thead>
<tr>
<th>Dangerous Components:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 7784-13-6</td>
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<tr>
<td></td>
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<tr>
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<tr>
<td>CAS: 7631-86-9</td>
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<tr>
<td></td>
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<tr>
<td>CAS: 7757-79-1</td>
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<tr>
<td>RTECS: TT 3700000</td>
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<td></td>
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<tr>
<td>CAS: 24634-61-5</td>
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Additional information:
The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

4. First Aid Measures

Description of first aid measures:

After inhalation:
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.

After skin contact:
Immediately rinse with water.
If skin irritation occurs, consult a doctor.

After eye contact:
Rinse opened eye for several minutes under running water. Then consult a doctor. If easy to do so, remove contact lenses if worn.

After swallowing:
Do not induce vomiting without medical advice.
If swallowed and symptoms occur, consult a doctor.

Information for doctor:
Most important symptoms and effects, both acute and delayed: No further relevant information available.
Indication of any immediate medical attention and special treatment needed:
No further relevant information available.
5. Fire-Fighting Measures
   Extinguishing media:
   Suitable extinguishing agents: Use firefighting measures that suit the environment.
   Special hazards arising from the substance or mixture:
   During heating or in case of fire poisonous gases are produced.
   Advice for firefighters:
   Protective equipment:
   Mouth respiratory protective device.
   As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

6. Accidental Release Measures
   Personal precautions, protective equipment and emergency procedures:
   Mount respiratory protective device.
   Environmental precautions:
   Dilute with plenty of water.
   Do not allow to enter sewers/surface or ground water.
   Methods and material for containment and cleaning up:
   Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.
   Dispose of the collected material according to regulations.
   Reference to other sections:
   See Section 7 for information on safe handling.
   See Section 8 for information on personal protection equipment. See Section 13 for disposal information.
   Protective Action Criteria for Chemicals

<table>
<thead>
<tr>
<th></th>
<th>PAC-1:</th>
<th></th>
<th>PAC-2:</th>
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<th>PAC-3:</th>
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</tr>
<tr>
<td></td>
<td>7784-13-6 Aluminum Chloride Hexahydrate</td>
<td>54 mg/m3</td>
<td>7784-13-6 Aluminum Chloride Hexahydrate</td>
<td>110 mg/m3</td>
<td>7784-13-6 Aluminum Chloride Hexahydrate</td>
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<tr>
<td></td>
<td>7631-86-9 Silicon Dioxide</td>
<td>18 mg/m3</td>
<td>7631-86-9 Silicon Dioxide</td>
<td>740 mg/m3</td>
<td>7631-86-9 Silicon Dioxide</td>
</tr>
<tr>
<td></td>
<td>7757-79-1 Potassium Nitrate</td>
<td>9 mg/m3</td>
<td>7757-79-1 Potassium Nitrate</td>
<td>100 mg/m3</td>
<td>7757-79-1 Potassium Nitrate</td>
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</tbody>
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7. Handling and Storage
   Handling
   Precautions for safe handling:
   Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.
   Information about protection against explosions and fires: Keep protective respiratory device available.
   Conditions for safe storage, including any incompatibilities:
   Storage
   Requirements to be met by storerooms and receptacles: No special requirements.
   Information about storage in one common storage facility: Not required.
   Further information about storage conditions: None.
   Specific end use(s): No further relevant information available.

8. Exposure Controls / Personal Protection
   Additional information about design of technical systems: No further data; see section 7.
   Control parameters:
   Components with occupational exposure limits:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Additional information: The lists that were valid during the creation of this SDS were used as basis.

Exposure controls:

Personal protective equipment:

General protective and hygienic measures:
The usual precautionary measures for handling chemicals should be followed. Wash hands before breaks and at the end of work.

Breathing equipment: Not required.

Protection of hands:

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Select glove material based on penetration times, rates of diffusion and degradation.

Material of gloves: Rubber, latex or vinyl.

Penetration time of glove material: The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

Eye protection:

Safety glasses

9. Physical and Chemical Properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Pasty
Color: Light yellow
Odor: Odorless
Odor threshold: Not determined.

pH-value: Not applicable.

Change in condition
Melting point/Melting range: Not determined.
Boiling point/Boiling range: 400 °C (752 °F)

Flash point: None

Flammability (solid, gaseous): Not applicable.

Ignition temperature: Not applicable

Decomposition temperature: Not determined.

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined.
Upper: Not determined.

Vapor pressure: Not determined.

Density:

Relative density: Not determined.
**Vapor density:** Not determined.

**Evaporation rate:** Not determined.

**Solubility in / Miscibility with:**
- Water: Fully miscible.

**Partition coefficient (n-octanol/water):** Not determined.

**Viscosity:**
- Dynamic: Not determined.
- Kinematic: Not determined.

**Solvent content:**
- Organic solvents: 0.0%
- Solids content: 36.0%

**Other information:** No further relevant information available.

**10. Stability and Reactivity**

**Reactivity:** No further relevant information available.

**Chemical stability:** Stable under normal conditions.

**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**Possibility of hazardous reactions:** No dangerous reactions known.

**Conditions to avoid:** Extreme heat

**Incompatible materials:** Strong caustics, metal, acids

**Hazardous decomposition products:** No dangerous decomposition products known.

**11. Toxicological Information**

**Information on toxicological effects:**

**Acute toxicity:**

<table>
<thead>
<tr>
<th>LD/LC50 values that are relevant for classification:</th>
<th>7631-86-9 Silicon Dioxide</th>
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</thead>
<tbody>
<tr>
<td>Oral/Dermal/Lesional</td>
<td>LD50/50/50</td>
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<tr>
<td></td>
<td>LC50/4 h</td>
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<tr>
<td></td>
<td>Inhalative</td>
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<tr>
<th>7757-79-1 Potassium Nitrate</th>
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</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
</tbody>
</table>

**Primary irritant effect:**

**On the skin:** No irritating effect.

**On the eye:** Irritating effect.

**Additional toxicological information:**

**Carcinogenic categories:**

<table>
<thead>
<tr>
<th>IARC (International Agency for Research on Cancer):</th>
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<tbody>
<tr>
<td>7631-86-9 Silicon Dioxide</td>
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</table>

<table>
<thead>
<tr>
<th>NTP (National Toxicology Program):</th>
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<tbody>
<tr>
<td>None of the ingredients are listed.</td>
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</table>

<table>
<thead>
<tr>
<th>OSHA-Ca (Occupational Safety &amp; Health Administration):</th>
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<tbody>
<tr>
<td>None of the ingredients are listed.</td>
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</table>

**12. Ecological Information**

**Toxicity:**

**Aquatic toxicity:**

<table>
<thead>
<tr>
<th>7631-86-9 Silicon Dioxide</th>
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</tr>
</thead>
</table>
EC50 >1000 mg/l (Daphnia) (OECD 202)

7757-79-1 Potassium Nitrate

EC50 226 mg/l (Water flea)

Persistence and degradability: No further relevant information available.

Behavior in environmental systems:
Bioaccumulative potential: No further relevant information available.
Mobility in soil: No further relevant information available.

Additional ecological information:
General notes:
Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects: No further relevant information available.

13. Disposal Considerations

Waste treatment methods:
Recommendation:
Observe all federal, state and local environmental regulations when disposing of this material.

Uncleaned packagings
Recommendation: Disposal must be made according to official regulations.
Recommended cleansing agent: Water, if necessary with cleansing agents.

14. Transport Information

UN-Number:
DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

UN proper shipping name:
DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

Transport hazard class(es):
DOT, ADR/ADN, ADN, IMDG, IATA Non-Regulated Material

Class:
Non-Regulated Material

Packing group:
DOT, ADR/ADN, IMDG, IATA Non-Regulated Material

Environmental hazards:
Not applicable.

Special precautions for user:
Not applicable.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:
Not applicable.

UN "Model Regulation":
Non-Regulated Material

15. Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture:

SARA (Superfund Amendments and Reauthorization):

Section 355 (extremely hazardous substances):
None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):

7757-79-1 Potassium Nitrate

TSCA (Toxic Substances Control Act):

7631-86-9 Silicon Dioxide
7757-79-1 Potassium Nitrate
1934-21-0 FD&C Yellow No. 5
24634-61-5 Potassium Sorbate

California Proposition 65:

Chemicals known to cause cancer:
None of the ingredients are listed.
### Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed.

### Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.

### Chemicals known to cause developmental toxicity:
None of the ingredients are listed.

### New Jersey Right-to-Know List:
- **7757-79-1** Potassium Nitrate

### New Jersey Special Hazardous Substance List:
None of the ingredients are listed.

### Pennsylvania Right-to-Know List:
- **7631-86-9** Silicon Dioxide
- **7757-79-1** Potassium Nitrate

### Pennsylvania Special Hazardous Substance List:
None of the ingredients are listed.

### Carcinogenic categories:
- **EPA (Environmental Protection Agency):**
  None of the ingredients are listed.
- **TLV (Threshold Limit Value established by ACGIH):**
  None of the ingredients are listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health):**
  None of the ingredients are listed.

### GHS label elements
The product is classified and labeled according to the Globally Harmonized System (GHS).

#### Hazard pictograms:

- ![GHS07](image)

#### Signal word: Warning

#### Hazard-determining components of labeling:
- Aluminum Chloride Hexahydrate

#### Hazard statements:
- H315+H319 Causes skin and eye irritation.

#### Precautionary statements:
- **P280** Wear protective gloves.
- **P264** Wash thoroughly after handling.
- **P305+P351+P338** If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- **P321** Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
- **P332+P337** If skin irritation occurs: Get medical advice/attention.
- **P337+P313** If eye irritation persists: Get medical advice/attention.
- **P302+P352** IF ON SKIN: Wash with plenty of water.
- **P362+P364** Take off contaminated clothing and wash it before reuse.

### National regulations:
The product is subject to be classified according to the latest version of the regulations on hazardous substances.

### Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.
16. Other Information

Premier’s revision date: 06/26/2017
Revision Number: 10

Abbreviations and acronyms:
ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFP: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety and Health
OSHA: Occupational Safety & Health Administration
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Ox. Sol. 3: Oxidizing solids – Category 3
Skin Corr. 1A: Skin corrosion/irritation – Category 1A
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
* Data compared to the previous version altered.

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Supplier’s number: 030517

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