

SAFETY DATA SHEET

Traxodent® Hemostatic Retraction Paste System

1. Chemical Product and Company Identification

Trade Name: Traxodent® Hemostatic Retraction Paste 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)



HMIS-ratings (scale 0 - 4)



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.

Dangerous Components:		
CAS: 7784-13-6	Aluminum Chloride Hexahydrate	15-35%
	⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318	
CAS: 7631-86-9	Silicon Dioxide	5-10%
	⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H319	
CAS: 7757-79-1 RTECS: TT 3700000	Potassium Nitrate	≤ 5%
	⚠ Ox. Sol. 3, H272	
CAS: 24634-61-5	Potassium Sorbate	≤ 2.5%
	⚠ Eye Irrit. 2A, H319	

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

PAC-1:		
7784-13-6	Aluminum Chloride Hexahydrate	54 mg/m ³
7631-86-9	Silicon Dioxide	18 mg/m ³
7757-79-1	Potassium Nitrate	9 mg/m ³
PAC-2:		
7784-13-6	Aluminum Chloride Hexahydrate	110 mg/m ³
7631-86-9	Silicon Dioxide	740 mg/m ³
7757-79-1	Potassium Nitrate	100 mg/m ³
PAC-3:		
7784-13-6	Aluminum Chloride Hexahydrate	650 mg/m ³
7631-86-9	Silicon Dioxide	4,500 mg/m ³
7757-79-1	Potassium Nitrate	600 mg/m ³

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:

LD/LC50 values that are relevant for classification:		
7631-86-9 Silicon Dioxide		
Oral	LD50	10000 mg/kg (Rat) (OECD 401)
Dermal	LD50	5000 mg/kg (Rabbit) (OECD 402)
Inhalative	LC50/4 h	>140->2000 mg/l (Rat) (OCED 403) Maximum attainable concentration, mortality does not appear. 10000 mg/l (Zebra fish) (OECD 203)
7757-79-1 Potassium Nitrate		
Oral	LD50	3750 mg/kg (Rat)

Primary irritant effect:

On the skin: No irritating effect.

On the eye: Irritating effect.

Additional toxicological information:

Carcinogenic categories:

IARC (International Agency for Research on Cancer):		
7631-86-9	Silicon Dioxide	3
NTP (National Toxicology Program):		
None of the ingredients are listed.		
OSHA-Ca (Occupational Safety & Health Administration):		
None of the ingredients are listed.		

12. Ecological Information

Toxicity:

Aquatic toxicity:
7631-86-9 Silicon Dioxide

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

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
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TSCA (Toxic Substances Control Act):

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

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. |

National regulations:

The product is subject to be classified according with 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: 09/19/2021

Revision Number: 11

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)

NFPA: 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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