SAFETY DATA SHEETS

This SDS packet was issued with item:

078932105

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078932106



Safety Data Sheet According to HCS, 29 CFR 1910.1200

SECTION I. IDENTIFICATION

Product Identifier Product Name: Ionic Hemostatic Mineral Trade Name: ClotIt, Fermata Hemostatic Powder Product Form: Powder Mixture

Recommended Use of the Product

The powder is intended to be used as a topical dressing for local management of bleeding wounds such as cuts, lacerations, and abrasions.

Name, Address, and Telephone of Responsible Party

Manufacturer Protégé Biomedical 7730 Laredo Drive Chanhassen, Minnesota USA Phone: (763) 300-0841 www.protegebiomedical.com

Emergency Telephone Number

Phone: (763) 300-0841

SECTION 2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

Classification (GHS-US) Skin Irrit. 2 H315 Eye Irrit. 2B H320 Label Elements GHS-US Labeling

Hazard Pictograms (GHS_US) Signal Word (GHS-US)

Hazard Statements (GHS-US)

Precautionary Statements (GHS-US)

GH507--Warning H315—Causes skin irritation H320—Causes eye irritation P264—Wash thoroughly after handling

P280—Wear protective gloves/protective clothing/eye protection/face protection P302 + PP352—If on skin: Wash with

plenty of soap and water P305 + P351 + P338—If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

to do so, continue rinsing. P321—Specific Treatment (see Section 4) P332 + P313—If skin irritation occurs: Get medical advice/attention

P337 + P313—If eye irritation persists: get medical advice/attention

P362—Take off contaminated clothing and wash before reuse

Other Hazards

Other Hazards Not Contributing to the Classification: Exposure may aggravate those with pre-existing eye, skin or respiratory conditions.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

The composition of this product is considered a trade secret based on the definitions 1900.1200(i)

SECTION 4. FIRST-AID MEASURES

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

Description of First Aid Measures

Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove loose particles, rinse immediately with plenty of water. Obtain medical attention if irritation develops or persist.

Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately seek medical attention. **General:** Causes serious eye irritation. Causes skin irritation.

Most Important Symptoms and Effects Both Acute and Delayed

Inhalation: May cause respiratory irritation.

Skin Contact: Causes skin irritation.

Eye Contact: Causes serious eye irritation.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

Indication of immediate medical attention and special treatment needed: If you

feel unwell, seek medical advice (show the label where possible).

SECTION 5. FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising from the Substance or Mixture:

Fire Hazards: Not considered flammable but may burn at high temperatures. **Explosion Hazard:** Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Special Protective Equipment—Advice for Firefighters

Precautionary Measures Fire: Not available

Firefighting Instructions: Use water spray or fog for cooling exposed containers. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Product: Forms aluminum oxide, sulfur dioxide and/or sulfur trioxide at temperatures above 760°C (1400°F) or when dry alum is encompassed in a fire involving other burning materials.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all contact with skin, eyes, or clothing. Avoid breathing (dust, vapor, mist, gas).

For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE). **Emergency Procedures:** Evacuate unnecessary personnel.

For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection. **Emergency Procedures:** Stop leak if safe to do so. Eliminate ignition sources. Ventilate area.

Environmental Precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

Methods and Material for Containment and Clean Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: Avoid generation of dust during clean-up of spills. Vacuum clean-up is preferred. If sweeping is required, use a dust suppressant.

SECTION 7. HANDLING AND STORAGE

Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Good housekeeping is needed during storage, transfer, handling and use of this material to avoid excessive dust accumulation. Protect from moisture.

Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Storage away from direct sunlight, extremely high or low temperatures, oxidizing agents, acids and incompatible materials.

Incompatible Materials: Strong bases.

Specific End Use(s)

Alum is used as a coagulating agent in municipal and industrial water and waste water treatment as an additive in papermaking.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTIONS

OSHA permissible exposure limit (PEL). American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV)

Control Parameters

PEL: Long term value: 15 (total), 5 (resp.) mg/m3

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

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Exposure Controls:

Personal Protective Equipment: Protective goggles. Gloves. Protective clothing. **Materials for Protective Clothing:** Chemically resistant materials and fabrics.

Hand Protection: Wear chemically resistant protective gloves.

Eye Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: Use NIOSH-approved dust mask if dust has the potential to become airborne.

Environmental Exposure Controls: Do not allow the product to be released into the environment.

Consumer Exposure Controls: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Brown to off-white powder or granules. Odor: Not available. Odor Threshold: Not available. **<u>pH:</u>** >2.9 @ 5% Melting Point: 86°C (186.8°F) Freezing Point: Not available. **Boiling Point:** 117°C (242.6°F) Flash Point: Not available. **Relative Evaporation Rate (butyl acetate=1):** Not available. Flammability (solid, gas): Not available. Lower Flammable Limit: Not available. Upper Flammable Limit: Not available. Vapor Pressure: Not available. Relative Vapor Density at 20°C: Not available. **Relative Density:** Not available. **Solubility:** Water : Complete Partition coefficient: n-octanol/water: Not available. Auto-ignition Temperature: Not available. **Decomposition Temperature:** Not available. Viscosity: Not available.

SECTION 10: STABILITY AND REACTIVITY

<u>Reactivity</u>: Hazardous reactions will not occur under normal conditions.

<u>Chemical Stability</u>: Stable under recommended handling and storage conditions (see section 7).

<u>Possibility of Hazardous Reactions</u>: Hazardous polymerization will not occur. **<u>Conditions to Avoid</u>**: Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials. Moisture.

Incompatible Materials: Strong bases.

Hazardous Decomposition Products: Oxides of aluminum. The decomposition products are corrosive and hazardous to health.

SECTION 11: TOXICOLOGICAL INFORMATION

Likely Routes of Exposure:

The likely routes of exposure for this product are skin contact, eye contact and inhalation. **Symptoms Related to Toxicological Characteristics**

Symptoms/Injuries After Inhalation: May cause respiratory irritation.

Symptoms/Injuries After Skin Contact: Causes skin irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Effects Related to Exposure

Skin Corrosion/Irritation: Causes skin irritation.
Serious Eye Damage/Irritation: Causes eye irritation.
Respiratory or Skin Sensitization: Not classified.
Germ Cell Mutagenicity: Not classified.
Teratogenicity: Not classified.
Carcinogenicity: Not classified.
Specific Target Organ Toxicity (Repeated Exposure): Not classified.
Reproductive Toxicity: Not classified.
Specific Target Organ Toxicity (Single Exposure): Not classified.
Aspiration Hazard: Not classified.
Chronic Symptoms: None expected under normal conditions of use.
Numerical Measures of Toxicity:
Not classified.
National Toxicity Program (NTP) Report on Carcinogens:
Not listed.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not classified Persistence and Degradability Not available Bioaccumulative Potential: Mobility in Soil: Not available Other Adverse Effects: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport.

SECTION 15: REGULATORY INFORMATION

Regulations:

This product is regulated by the US Food and Drug Administration when for human use. This product may also be used on animals. This product should be used in accordance with federal, state and local regulations.

SECTION 16: OTHER INFORMATION

<u>Revision Date</u>: 04/26/2016 (retyped 04/03/2019) <u>**Other Information**</u>: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200. <u>**Protégé Biomedical Document #**</u>: QMS-8800: Rev-0

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