

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Granuflo Dry Acid Blend Bag
Product Number:	None
Formula:	Mixture of inorganic salts and organic acid
Product Use:	For preparation of hemodialysis dialysate, for use as directed in product labeling.
Restrictions on Use:	For intended medical device use only. Do not use for direct administration, food use, or non-labeled applications.

SUPPLIER INFORMATION: Fresenius Medical Care, Renal Therapies Group, LLC

Address:
920 Winter Street
Waltham, MA 02451

Phone Number: 1-800-323-5188
Fax Number: N/A
Email Address: N/A

Emergency Contact Information:
CHEMTREC 1- 800-424-9300

2. HAZARDS IDENTIFICATION

CLASSIFICATION AND LABELING (GHS / HMIS / NFPA):

GHS Status		
Pictogram	Classification	Signal Word, Hazard Statements, Precautionary Statements
	Eye Irritation, Category 2A, H319	Warning: Causes Serious Eye Irritation P264+P265: Wash hands thoroughly after handling. Do not touch eyes. P280: Wear eye protection/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing. P337+P317: If eye irritation persists: Get medical help. Hazards Not Otherwise Classified: None.

POTENTIAL HEALTH EFFECTS

ACUTE EFFECTS:

Eye: Causes serious eye irritation.

Skin: Although not classified as hazardous to skin, overexposure associated with non-standard use may cause irritation.

Inhalation: Although not classified as hazardous by the inhalation route, overexposure associated with non-standard use may irritate the nose, throat and upper respiratory tract.

Ingestion: Although not classified as hazardous by ingestion, exposure to large quantities may cause gastrointestinal irritation, nausea and vomiting.

CHRONIC EFFECTS:

None expected.

3. COMPOSITION/INFORMATION ON INGREDIENTS OF BLEND BAG

Components	CAS No.	Weight % Range
Sodium Chloride	7647-14-5	83% – 86%
Sodium Diacetate	126-96-5	8%– 9%
Potassium Chloride	7447-40-7	0.8% – 4%
Calcium Chloride Dihydrate	10035-04-8	2% – 4%
Magnesium Chloride Hexahydrate	7791-18-6	1% – 2%

4. FIRST AID MEASURES

PROCEDURES

Eye Contact:	If in eyes: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if eye irritation persists.
Skin Contact:	Rinse affected area with water. Get medical attention if irritation, pain, swelling or other symptoms persist.
Inhalation:	Move to fresh air. Get medical attention if irritation or other symptoms persist.
Ingestion:	Contact a physician
Note to Physicians:	None known. Use general supportive care.

5. FIRE FIGHTING MEASURES

Unusual Fire and Explosion Hazards:	None.
Extinguishing Media:	Alcohol foam, water fog, carbon dioxide or dry chemical as appropriate for surrounding fire.
Special Firefighting Procedures:	Use procedures, protective clothing, breathing apparatus, and equipment appropriate for surrounding fire.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	In case of accidental bulk release, wear appropriate personal protective equipment (PPE), including goggles, respirator, boots, gloves, and clothing which covers exposed areas of the arms, legs and torso.
Environmental precautions:	Avoid dispersal of spilled material and runoff to the environment. Avoid contact with soil and waterways.
Methods and materials for containment:	Sweep, scoop or vacuum into a container.
Cleanup procedures:	Ventilate the area. Sweep, scoop or vacuum into a container. Thoroughly collect spilled material and dispose of in accordance with applicable waste laws.

7. HANDLING AND STORAGE

Handling:	Transport in original container in accordance with good industrial hygiene and safety practice. Use PPE in accordance with Section 8 of this SDS while handling. Avoid inhalation and contact with eyes and skin. Keep in the original container or an approved alternative made from a compatible material, keep tightly closed when not in use.
Storage:	Store protected from direct sunlight and away from other chemicals in a dry, cool, well-ventilated area, away from incompatible materials. Keep away from food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.
Other Precautions:	Refer to product instructions and label for further requirements for handling, storage and use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Product is a powder but contains no substances with occupational exposure limit values. OSHA PELs for particulates not otherwise regulated (PNOR) are 15 mg/m³ (total dust as 8-hour time-weighted average) and 5 mg/m³ (respirable fraction as 8-hour time-weighted average).

Engineering Controls:	Normal building ventilation.
Eye/Face Protection:	Safety glasses recommended.
Skin Protection:	Wear nitrile gloves and suitable clothing to prevent repeated or prolonged skin contact.
Respiratory Protection:	Not required through typical use.
General Hygiene Considerations:	Wash hands thoroughly after use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Value	Property	Value
Appearance:	White crystalline powder or granules	Initial Boiling Point (°F):	Not established
Odor:	Acetic Acid Odor	Boiling Range (°F):	Not established
Odor Threshold:	Not established	Melting point:	Not established
Molecular Weight:	Not established	Specific gravity (g/cc):	Not established
Physical State:	Solid (powder or granules)	Viscosity (cps):	Not established
pH:	Not Applicable	Flash Point:	Not established
Vapor Pressure (mm Hg):	Not established	Decomposition Temperature:	Not established
Solubility in Water (20°C):	Soluble	Flammability:	Not flammable
Volatiles, Percent by volume:	Not established	Upper/Lower Flammability Limits:	Not established
Vapor Density (air = 1):	Not established	Auto-ignition Temperature:	Not established
Evaporation Rate:	Not established	Octanol/water partition coefficient:	Not established
Relative Density:	Not established	Particle Characteristics:	Not established

10. STABILITY AND REACTIVITY

Stability:	Stable under normal conditions.
Reactivity:	Not reactive.
Conditions to Avoid:	Strong oxidizing solutions.
Materials to Avoid:	Strong oxidants.
Hazardous Decomposition Products:	None expected.
Hazardous Polymerization:	Will not occur.
Hazardous reaction conditions:	None known.

11. TOXICOLOGICAL INFORMATION

Potential Exposure Routes:	Skin, eye, inhalation, ingestion.
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ACUTE ANIMAL TOXICITY DATA:

Chemical Substance	Oral LD50 (mg/kg)	Dermal LD50 (mg/kg)	Inhalation LC50 (4-hour, mg/m ³)
Sodium Chloride	3000 in rat	>10,000 in rabbit	Not established
Sodium Diacetate	5600 in rat	>2000 in rat	Not established
Potassium Chloride	2600 in rat	Not established	Not established
Calcium Chloride	1000 to 4179 in rat	>2630 in rat	Not established
Magnesium Chloride	2800 in rat	Not established	Not established

Skin Corrosion/Irritation:	Prolonged and repeated exposure to product may cause mild skin irritation.
Eye Damage/ Irritation:	Causes Serious Eye Irritation.
Respiratory Irritation:	Not anticipated to be a respiratory irritant under normal use.
Germ Cell Mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive, Teratogenicity, or Developmental Effects:	Not classified
STOT- Single Exposure:	Not classified
STOT- Repeated Exposure:	Not classified
Aspiration Hazard:	Not classified
Neurological Effects:	None known
Interactions with Other Chemicals Which Enhance Toxicity:	None known

12. ECOLOGICAL INFORMATION

Ecotoxicity:	Not established.
Persistence and degradability:	Not established.

Bioaccumulative potential: Not established.

Mobility in soil: Not established.

Other adverse effects: Not established.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with Federal, State and/or local waste rules / regulations.

14. TRANSPORT INFORMATION

Regulation	UN #	Proper Shipping Name	Hazard Class	Packing Group
U.S DOT	None	Not Hazardous per DOT Criteria	None	None
TDG	None	Not Hazardous per TDG Criteria	None	None
IATA	None	Not Hazardous per IATA Criteria	None	None
IMDG	None	Not Hazardous per IMDG Criteria	None	None
ADR/RID	None	Not Hazardous per ADR/RID Criteria	None	None

Environmental Hazard (Marine Pollutant) No.

Special Precautions for transport: None known.

15. REGULATORY INFORMATION

Not mandatory

16. OTHER INFORMATION

The data included herein are presented according to Fresenius Medical Care practices current at the time of preparation hereof, are made available solely for the consideration, investigation and verification of the original recipients hereof and do not constitute a representation or warranty for which Fresenius Medical Care assumes responsibility. It is the responsibility of a recipient of this data to remain currently informed on chemical hazard information, to design and update its own safety program and to comply with all national, federal, state and local laws and regulations applicable to safety, occupational health, right to know and environmental protection.

As medical device subject to labeling under FDA, the product meets the requirements for the workplace labeling exemption in 29 CFR 1910.1200(b)(5)(iii). As such, this SDS is provided for workplace hazard communication, transport, and waste-management purposes.

REVISIONS: This SDS was prepared to conform to 29 CFR Parts 1910.1200(g), 1915.1200 and 1926.59, known as Hazard Communication (HazCom) Standard.

Revision Date: 07/16/2026. Supersedes: July 2, 2015. Sections 1 – 9, 11-12, and 14 – 16 have been updated.

PREPARED BY: Fresenius Medical Care, Renal Therapies Group, LLC