

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	NaturaLyte Liquid Acid Concentrate (45X) (0000 through 4000 Series)
Product Number:	None
Formula:	Mix of inorganic salts, salts, and sugar
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	GHS Classification	Signal Word, Hazard Statements, Precautionary Statements
	Eye Irritation, Category 2B, H320 Corrosive to Metals, H290	Warning: Causes Eye Irritation, May be Corrosive to Metals. P264: Wash hands/face thoroughly after handling. Do not touch eyes. 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. P234: Keep only in original container. P390: Absorb spillage to prevent material damage. P406: Store in corrosive resistant container with a resistant inner liner. Hazards Not Otherwise Classified: None.

POTENTIAL HEALTH EFFECTS

ACUTE EFFECTS:

Eye: Causes 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

Components	CAS No.	Weight % Range
Sodium Chloride	7647-14-5	20% - 25%
Dextrose	50-99-7	3% – 5%
Potassium Chloride	7447-40-7	< 2%
Acetic Acid	64-19-7	< 2%
Calcium Chloride Dihydrate	10035-04-8	<1%
Magnesium Chloride Hexahydrate	7791-18-6	<1%
Water	7732-18-5	>64%

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:	Call a poison center or physician if symptoms develop or persist.
Note to Physicians:	None known. Use general supportive care.

5. FIRE FIGHTING MEASURES

Unusual Fire and Explosion Hazards:	None known.
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, 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:	Absorb spillage to prevent material damage.
Cleanup procedures:	Thoroughly collect spill with absorbent material and dispose in accordance with applicable hazardous 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:** Keep only in original packaging. Do not store in aluminum containers. Store protected from direct sunlight and away from other chemicals in a dry, cool, well-ventilated area, away from incompatible materials, including aluminum. 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

Component	OSHA Permissible Exposure Limits (PELs)	American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs)	NIOSH Recommended Exposure Limits (RELs)
Sodium Chloride	Not established	Not established	Not established
Dextrose	Not established	Not established	Not established
Potassium Chloride	Not established	Not established	Not established
Acetic Acid	10 ppm (25 mg/m ³) TWA	10 ppm (25 mg/m ³) TWA; 15 ppm (37 mg/m ³) (STEL)	10 ppm (25 mg/m ³) TWA; 15 ppm (37 mg/m ³) (STEL)
Calcium Chloride	Not established	Not established	Not established
Magnesium Chloride	Not established	Not established	Not established

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	Value	Property	Value
Appearance:	Clear aqueous solution	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:	Liquid	Viscosity (cps):	Not established
pH:	1.8 – 2	Flash Point:	Not established

Property	Value	Property	Value
Vapor Pressure (mm Hg):	Not established	Decomposition Temperature:	Not established
Solubility in Water (20°C):	Completely	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 under normal conditions.
Conditions to Avoid:	Strong oxidizing solutions.
Materials to Avoid:	Strong oxidants.
Hazardous Decomposition Products:	No hazardous decomposition products are expected under normal conditions of use. Exposure to fire or elevated temperatures may produce carbon dioxide gas (CO ₂). Contact with incompatible materials, including bicarbonates and other carbonate-containing compounds, may result in the evolution of carbon dioxide (CO ₂) gas.
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
Dextrose	Not evaluated	Not evaluated	Not evaluated
Potassium Chloride	2600 in rat	Not established	Not established
Acetic Acid	3310 to 3530 in rat	1060 in rat	11.4
Calcium Chloride	1000 to 4179 in rat	>5000 in rat	Not established
Magnesium Chloride	2800 in rat	Not established	Not established

Skin Corrosion/Irritation: In vitro OECD TG 435/Corrositex testing of Citrasate Liquid reported no biobarrier breakthrough after 75 minutes; however prolonged and repeated exposure to product may cause mild skin irritation.

Eye Damage/ Irritation: Causes 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

When discarded in its unused or undiluted form, this product meets the definition of a corrosive hazardous waste (RCRA D002). 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	3265	Corrosive Liquid, Acidic, Organic n.o.s. (Acetic Acid)	8	III
TDG	3265	Corrosive Liquid, Acidic, Organic n.o.s. (Acetic Acid)	8	III
IATA	3265	Corrosive Liquid, Acidic, Organic n.o.s. (Acetic Acid)	8	III
IMDG	3265	Corrosive Liquid, Acidic, Organic n.o.s. (Acetic Acid)	8	III
ADR/RID	3265	Corrosive Liquid, Acidic, Organic n.o.s. (Acetic Acid)	8	III

Classified due to corrosive effect on aluminum only and meets requirements for exemption in 49 CFR 173.154 (d)(1) for US transport by motor vehicle or rail car in compatible packaging.

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 – 4, 6 -14, and 16 have been updated.

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