

MATERIAL SAFETY DATA SHEET

Kionex Suspension USP 15g/60mL

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SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Kionex Suspension USP 15g/60mL
COMMON NAME: Sodium Polystyrene Sulfonate Suspension
CHEMICAL NAME: N/A
SYNONYMS: N/A
CHEMICAL FORMULA: N/A
CHEMICAL FAMILY: Antihyperkalemic

SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% w/w	OSHA PEL	ACGIH TLV	IDLH
Sodium Polystyrene Sulfonate	25704-18-1	<25	NE	NE	NE
Purified Water, USP	7732-18-5	<50	NE	NE	NE
Magnesium Aluminum Silicate, NF	mixture	<10	15mg/m ³ total dust	NE	NE
Xanthan Gum	11138-66-2	<1	NE	NE	NE
Methylparaben, NF	99-76-3	<1	NE	NE	NE
Propylparaben, NF	94-13-3	<1	NE	NE	NE
Sorbic Acid, NF	110-44-1	<1	NE	NE	NE
Sorbitol Solution 70%, USP	50-70-4	<50	NE	NE	NE
Sodium Saccharin, USP	128-44-9	<1	NE	NE	NE
Propylene Glycol	57-55-6	<10	NE	400 ppm	NE
Flavor – Raspberry Blend	mixture	<10	NE	NE	NE

NE = Not Established

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Kionex Suspension (oral solution) is a brown liquid with a raspberry flavor. The ingredients listed are non-hazardous.

Symptoms of Overexposure by Route of Exposure: Excess ingestion may cause gastric irritation, anorexia, nausea, vomiting, constipation, hypokalemia, hypocalcemia, and sodium retention. Possible diarrhea, fecal impaction and intestinal obstruction

Inhalation: No adverse effects expected under normal conditions of use.

Contact with Skin or Eyes: In case of contact with skin wash with a mild soap and water. In case of eye contact immediately flush with copious amounts of water for 15 minutes and seek emergency medical treatment.

Ingestion: Medical personnel are not anticipated to experience over-exposures to therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: Not Known

Chronic: Not Known

Medical Conditions Aggravated by Over Exposure: This product is contraindicated for patients with hypokalemia or those who are hypersensitive to it. Serious potassium deficiency can occur from Sodium Polystyrene Sulfonate therapy.

Other Comments: Sodium Polystyrene Sulfonate suspension can cause electrolyte disturbances and systemic alkalosis.

Pre-Existing Medical Conditions: Caution is advised when Sodium Polystyrene Sulfonate is administered to patients who cannot tolerate even a small increase in sodium loads, like severe congestive heart failure, severe hypertension, or marked edema.

SECTION 4: FIRST AID MEASURES

Skin Exposure: Thoroughly wash with mild soap and water. If irritation develops seek medical attention.

Eye Exposure: Flush eye with copious amounts of water and seek medical attention immediately.

Inhalation: Inhalation exposure is not expected to occur.

Ingestion: For overexposure, seek medical attention.

SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flash Point: NA

Autoignition Temperature: NA

Flammable Limits (in air by volume, %): Lower: NA Upper: NA

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK **Carbon Dioxide:** OK **Halon:** OK

Foam: OK **Dry Chemical:** OK **Other:** Any "ABC" Class

Boiling Point:	ND	Vapor Pressure:	ND
Melting/Freezing Point:	ND	pH:	5
Water Solubility:	Partial	Water Reactive:	No
Specific Gravity (Water =1):	1.24	Evaporation Rate (Butyl acetate = 1):	ND
Appearance/Odor:	Kionex Suspension (oral solution) is a brown liquid with a raspberry flavor.		
ND = No Data			

SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable under labeled storage conditions.
Incompatible Materials:	This product is generally compatible with other common materials in a medical facility.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Protect from light and excessive heat.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Kionex Suspension (Sodium Polystyrene Sulfonate Suspension, USP).

Oral LD50 = ND

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: No Data

Sensitization to the Product: No Data

Reproductive Toxicity Information: Listed below is information concerning the effects of Sodium Polystyrene Sulfonate Suspension on human and animal reproductive systems. This material is classified as a Pregnancy Category C (Risk to Fetus Cannot be Ruled-Out).

Mutagenicity: ND

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Kionex suspension is a Pregnancy Category C. Animal reproductive studies have not been conducted with Sodium Polystyrene Sulfonate. It is also not known whether Sodium Polystyrene Sulfonate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Polystyrene Sulfonate should be given to a pregnant woman only if clearly needed. It is not known whether Sodium Polystyrene Sulfonate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Polystyrene Sulfonate is administered to a nursing woman.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

SECTION 12: ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Sodium Polystyrene Sulfonate suspension on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effects of Sodium Polystyrene Sulfonate suspension on aquatic life.

EC 50 (Daphnia: Daphnia magna) / 48h: ND

SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA “listed” or “characteristic” hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

SECTION 14: TRANSPORTATION INFORMATION

This Material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

SECTION 15: REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Kionex Suspension (Sodium Polystyrene Sulfonate) is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1. Provided to Summarize Occupational Exposure Hazards):

WARNING! Kionex Suspension (Sodium Polystyrene Sulfonate) should be administered under the supervision of a qualified physician.

SECTION 16: OTHER INFORMATION

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC ₅₀ :	Medial Lethal Concentration
LD ₅₀ :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average