



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Potassium Chloride, 20 mEq, Powder for Oral Solution, USP, 1.5 grams. Pouch	NDC 64950-321-20
Potassium Chloride, 20 mEq, Powder for Oral Solution, USP, 1.5 grams, Carton of 30 pouches	NDC 64950-321-30
Potassium Chloride, 20 mEq, Powder for Oral Solution, USP, 1.5 grams, Carton of 100 pouches	NDC 64950-321-01

Recommended use:

Indicated for the treatment and prophylaxis of hypokalemia in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient. Dilute with at least 4 ounces of cold water. Take with meals or immediately after eating.

Restrictions:

If serum potassium concentration is <2.5 mEq/L, use intravenous potassium instead of oral supplementation. It's contraindicated in patients on potassium sparing diuretics. Pediatric patients aged birth to 16 years old typical dose is 1 mEq/kg/day. Do not exceed 3 mEq/kg/day.

Manufacturer Name:

Genus Lifesciences Inc.

Manufacturer Address:

514 N. 12th Street
Allentown, PA 18102

Fax number:

(610) 782-9781

Telephone number:

(610) 782-9780 ext.*100

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

This product is a non-hazardous pharmaceutical mixture and does not meet OSHA's Globally Harmonized System (GHS) hazard criteria.

Signal Word:

Not Applicable

Hazard Statement:

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System (GHS).

Pictogram:

Not Applicable

Precautionary Statement:

Generally safe at recommended doses. Dilute before use. Avoid contact with eyes. Seek medical attention in case of accidental exposure or overdose.

Hazards Not Otherwise Classified:

Common effects may include nausea, vomiting, abdominal pain or discomfort, and diarrhea. Do not administer full strength, it may cause gastrointestinal irritation if administered undiluted.



SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Citric Acid Anhydrous	Not Available	77-92-9
Colloidal Silicon Dioxide, NF	Chromosorb, Crystalline Silica	99439-28-8
FD&C Yellow #6	Sunset Yellow FCF, E110	2783-94-0
Natural and Artificial Orange Flavor	N/A	N/A
Potassium Chloride (Active Ingredient)	Sylvite	7447-40-7
Sucralose	Trichlorosucrose, Aspasvit	56038-13-2

* Chemical exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 – FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.

Skin Contact: Wash with soap and large amount of water. Contact medical personnel if irritation persists.

Ingestion: This product is intended to be diluted for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician or a Poison Control Center (1-800-222-1222) immediately.

Inhalation: Move to fresh air. Get medical attention if symptoms persist.

Symptoms or effects: The main possible effect of over dosage is hyperkalemia, which is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5 to 8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segments, and prolongation of the QT intervals). Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9 to 12 mEq/L).

Recommendations: Immediate medical attention is required if overdose is suspected. Eliminate foods and medications containing potassium and of any agents with potassium-sparing properties such as diuretics, NSAIDs, and certain nutritional supplements.

Note to Physician: Treatment measures for hyperkalemia include monitor closely for arrhythmias and electrolyte changes, administer intravenous calcium gluconate if the patient is at no risk or low risk of developing digitalis toxicity, administer intravenously 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1000 mL, and correct acidosis, if present, with intravenous sodium bicarbonate.



SECTION 5 – FIREFIGHTING MEASURES

- Extinguishing media:** Use carbon dioxide, dry chemical, or water spay. Use water spray to cool unopened containers.
- Specific hazards arising from the mixture:** None known. (Refer to section 10)
- Advice to the firefighters:** Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Personal Precautions:** Clean the spill if it is safe to do so. Minimize exposure. Avoid inhalation of dust.
- Protective Equipment:** Safety Glasses or goggles, gloves, protecting clothes, dust mask or respirator.
- Emergency procedures:** Evacuate the area and keep unauthorized personnel away. Prevent further leakage or spillage if safe to do so. Keep upwind.
- Containment Precautions:** Isolate area around spill as specified by site procedures.
- Clean Up Procedures:** Sweep up and place in a clearly labeled container for chemical waste. Collect and place the material used in a compatible container. Dispose according to applicable regulations. Decontaminate the area with water.

SECTION 7 – HANDLING AND STORAGE

- Precaution for safe handling:** Observe safe industrial practices. No special handling requirements for normal use of this material. Dispense in a tight, light-resistant container as defined in the USP.
- Conditions for safe storage:** Store at Controlled Room Temperature, 25°C (77°F); excursions are permitted to 15° - 30°C (59° - 86°F). Protect from light.
-



SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

The exposure limits listed below are for the active ingredient Potassium Chloride (KCl) and not for the powder product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	1110 µg/m ³
Acceptable Daily Exposure (ADE):	5560 µg/day
Band System Exposure Classification:	Category 1 – Low Risk
ACGIH Short Term Exposure Limits (STEL):	Not Available
ACGIH Threshold Limit Values (TLVs):	Not Available
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Good ventilation should be use. Ventilation should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Measures:

Respiratory protection:	In case of inadequate ventilation use suitable respirator. During dust-raising work use a dust mask/respirator.
Eye protection:	Wear safety glasses or goggles if eye contact is possible or dust is generated. Provide an eye wash station when needed.
Protective gloves:	Not required under normal conditions of use. Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use.
Hygiene measures:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Wash clothing and protective equipment to remove contaminants.
Other personal protection:	None required



SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Light pink to orange powder	Odor:	Orange
Density:	0.98 – 1.04 g/ml	Boiling Point:	Not Available
Melting Point:	Not Applicable	Solubility:	Soluble in
Water.Slightly	soluble in Alcohol		
Viscosity:	Not Available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	Not Available	Flash Point:	Not Available
Reactivity:	Refer to section 10	Toxicity:	Refer to section 11

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid: Excessive heat.

Incompatible materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products: None known



SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Ingestion

Delayed, immediate and chronic effects for short and long term exposure:

General effects:	Nausea, vomiting, abdominal pain or discomfort, and diarrhea.	
Sensitization:	No data available	
Mutagenic effects:	No data available	
Reproductive toxicity:	No data available, but is unlikely potassium supplementation that does not lead to hyperkalemia (high potassium levels) would affect reproductive capacity.	
Fetotoxic / Teratogenic Effects:	No data available, but is unlikely potassium supplementation that does not lead to hyperkalemia (high potassium levels) would have an adverse effect on the fetus.	
Specific target organ toxicity (STOT):		
	Single exposure:	No data available
	Repeated exposure:	No data available

Toxicity (LD50):

The toxicity information listed below is for the active ingredient Potassium Chloride (KCl) and not for the Powder product itself.

Oral LD50 Rat:	2600 mg/kg
Oral LD50 Mouse:	1500 mg/kg

Symptoms / Adverse Reactions:

The most common adverse reactions to oral Potassium Salts are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea. Use with Potassium-sparing diuretics can produce severe hyperkalemia. NSAIDs may produce Potassium retention by reducing renal synthesis of prostaglandin E and impairing the renin-angiotensin system. Closely monitor Potassium in patients on concomitant NSAIDs.

Carcinogenicity:

Not listed as a carcinogen by OSHA



SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects):	Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.
Persistence and Degradability:	No data available
Bioaccumulation:	No data available
Leaching studies:	Not Available
Other adverse effects:	The product is not classified as environmentally hazardous.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers:	Dispose used or contaminated containers in accordance with the federal, state or local regulatory requirements.
Waste Disposal Methods:	Dispose in accordance with the federal, state or local regulatory requirements.
Special Precautions:	Discard away from children's reach. Releases to the sewer should be avoided.

SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

ICAO - International Civil Aviation Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO.

IATA - International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known



SECTION 15 – REGULATORY INFORMATION

Food and Drug Administration (FDA):	Approved prescription medication
Drug Enforcement Administration (DEA):	Not Listed as Controlled Substances.
SARA 302/304 Extreme Hazardous Substances (EHS):	Not Applicable
SARA 311/312 Hazard Categories:	Not Applicable
SARA 313 Toxic Chemical Release Inventory (TRI):	Not Applicable
Resource Conservation and Recovery Act (RCRA):	No Code Applicable
Clean Water Act (CWA):	

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following product ingredients are included on the TSCA inventory 8(b):

Ingredient	CAS No
Citric Acid Anhydrous	77-92-9
FD&C Yellow	2783-94-0
Potassium Chloride	7447-40-7

There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.



SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Jun/23/2015, New SDS

Revision Date: Mar/11/21

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

Genus Lifesciences Inc. believes that the information contained herein is based on the best available data at the date of preparation. However, no warranty is expressed or implied regarding the data's accuracy and completeness. Since the use of this information and the conditions of use of this material are not within the control of Genus Lifesciences Inc., it is the user's obligation to determine the conditions of safe use of this material.