SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Potassium Chloride Oral Solution, USP, 20 meq/15 ml, 30 gallons	NDC 64950-320-99
Potassium Chloride Oral Solution, USP, 20 meq/15 ml, 473 ml bottle	NDC 64950-320-47
Potassium Chloride Oral Solution, USP, 40 meq/15 ml, 473 ml bottle	NDC 64950-322-47

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.

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.

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SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Citric Acid Anhydrous	Not Available	77-92-9
FD&C Yellow #6	Sunset Yellow FCF, E110	2783-94-0
Glycerin	Glycerol, Propanetriol	56-81-5
Natural and Artificial Orange Flavor	Not Available	Not Available
Potassium Chloride (Active Ingredient)	Sylvite	7447-40-7
Purified Water	Not Available	7732-18-5
Sodium Benzoate	Benzoic acid, sodium salt Sobenate Antimol	532-32-1
Sodium Citrate Dihydrate	Citric acid trisodium salt	6132-04-3
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 for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician immediately.

Inhalation: Not an expected route of exposure.

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 is safe to do so. Minimize exposure.

Protective Equipment: Safety Glasses or goggles, gloves, protecting clothes.

Emergency procedures: Evacuate the area. Prevent further leakage or spillage if safe to do so.

Containment Precautions: Isolate area around spill as specified by site procedures.

Clean Up Procedures: Absorbed the liquid with suitable absorbent material. 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 and freezing.

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 Oral Solution 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: Not required when handling liquid or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Personal Protective Measures:

Respiratory protection:	None required when handling liquids.
Eye protection:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
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:	Wash hands thoroughly.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Clear orange liquid	Odor:	Orange
Density:	0.87 – 0.94 g/ml	Boiling Point:	Not available
Melting Point:	Not Applicable	Solubility:	In water
Viscosity:	Not available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	2.0 – 5.0	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 cold, freezing.
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: Paralysis, cardiac arrest.

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 Oral Solution product itself.

Oral LD50 Rat: 2600 mg/kg

Oral LD50 Mouse: 1500 mg/kg

Symptoms / Adverse Reactions: Nausea, vomiting, abdominal pain or discomfort, and diarrhea. It may cause gastrointestinal irritation if administered undiluted. This product is known to be excreted by the kidney, and the risk of reactions may be greater in patients with impaired renal function.

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. No harmful effects to aquatic organisms are expected.

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 of waste 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

TSCA - Toxic Substances Control Act 8(b): Not applicable for the product. Some of the ingredients are included on the TSCA inventory.

Drug Enforcement Administration (DEA): Not Listed as Controlled Substances.

Food and Drug Administration (FDA): Approved prescription medication

SARA 311/312 Hazard Categories: Not Applicable

CWA - Clean Water Act:

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)

CERCLA - Environmental Response Compensation and Liability Act:

This material, as supplied, does not contain any 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.

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Jul/17/2014, New SDS

Revision Date: Feb/10/21

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

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