



# 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. 12<sup>th</sup> 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

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

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

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|                                 |                                                                                                                                                                                                                      |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal Precautions:</b>    | Clean the spill if it is safe to do so. Minimize exposure. Avoid inhalation of dust.                                                                                                                                 |
| <b>Protective Equipment:</b>    | Safety Glasses or goggles, gloves, protecting clothes, dust mask or respirator.                                                                                                                                      |
| <b>Emergency procedures:</b>    | Evacuate the area and keep unauthorized personnel away. Prevent further leakage or spillage if safe to do so. Keep upwind.                                                                                           |
| <b>Containment Precautions:</b> | Isolate area around spill as specified by site procedures.                                                                                                                                                           |
| <b>Clean Up Procedures:</b>     | 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

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|                                      |                                                                                                                                                                            |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Precaution for safe handling:</b> | 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. |
| <b>Conditions for safe storage:</b>  | Store at Controlled Room Temperature, 25°C (77°F); excursions are permitted to 15° - 30°C (59° - 86°F). Protect from light.                                                |

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## SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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### 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 <sup>3</sup> |
| 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

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### 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

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**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

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**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

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

## SECTION 13 – DISPOSAL INFORMATION

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

## SECTION 14 – TRANSPORT INFORMATION

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### **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

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

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):

| <b>Ingredient</b>     | <b>CAS No</b> |
|-----------------------|---------------|
| 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**

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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.

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