

1. Product and Company Identification

Product identifier: Potassium Chloride for Oral Solution, USP 20 mEq

Other means of identification: - Potassium Chloride for Oral Solution, USP 20mEq

Recommended use: - Medicinal Product

This Safety Data Sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician.

Manufacturer information and Address: GRANULES PHARMACEUTICALS, INC.

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2. Hazard(s) identification

Hazard Overview

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.



3. Composition/information on ingredients

Name	CAS Number	%by Weight
Potassium Chloride, USP	7447-40-7	94.63 %
Anhydrous Citric Acid, USP	77-92-9	*
Sucralose, USP/NF	56038-13-2	*
Orange Flavor, Natural and Artificial	N/A	*
Colloidal Silicon Dioxide, NF	112945-52- 5/7631-86-9	*
FD&C Yellow #6	2783-94-0	*

Additional information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

<u>Ingredients in composition:</u> Potassium Chloride, USP, Anhydrous Citric Acid, USP, Sucralose, USP/NF, Orange Flavor, Natural and Artificial, Colloidal Silicon Dioxide, NF and FD&C Yellow#6.

4. First-aid measures

Eyes: Rinse with water. Get medical attention if irritation develops and persists

Skin: Rinse skin with water/shower. Get medical attention if irritation develops and persists. **Ingestion:** Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.



Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

5. Fire-fighting measures

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials water, foam, dry chemical or CO2.

Special hazards arising from the substance or mixture: Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential explosion hazard.

Advice for firefighters: Wear self-contained breathing apparatus and full protective turnout gear. Evacuate area and fight fire from a safe distance

Further information: No data available.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Avoid breathing dust. Provide adequate ventilation.

Environmental precautions: Do not let product enter drains.

Methods and materials for containment and cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and storage

Handling: Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid prolonged or repeated exposure. **Storage:** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature] to ensure product integrity.

8. Exposure controls/personal protection

Engineering controls: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits (0.005mg/m³)

Personal protective equipment



Eye/face protection: Safety glasses

Skin protection: Chemically compatible gloves.

Body Protection: Lab coat

Respiratory protection: Where respirators are deemed necessary to reduce or control occupational

exposures, use NOISH-approved under appropriate government standards (US).

Control of environmental exposure: Do not let product enter drains.

Exposure Limits: Not available.

9. Physical and chemical properties

Physical state: Solid

Form: Each Pouch Contains light pink to orange powder with colored speckles.

Molecular Formula: Mixture **Molecular Weight:** Mixture

10. Stability and Reactivity

Chemical Stability: Stable under recommended storage condition (See the Label).

Conditions to Avoid: Heat, sparks, and flame

Incompatibilities with Other Materials: Strong oxidizing agents.

Hazardous Decomposition Products: Nitrogen oxides

11. Toxicological information

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End point, Dose)

Potassium Chloride, USP

Rat Oral LD50 2600mg/kg

Anhydrous Citric Acid, USP

Rat Oral LD50 3000mg/kg



Sucralose

Rat Oral LD50 10000mg/kg

Orange Flavor, Natural and Artificial

Rat Oral LD50 5000mg/kg

Colloidal Silicon Dioxide, NF

Rat Oral LD50 >5000mg/kg

FD&C Yellow #6

Rat Oral LD50

Mouse Oral LD50 5000mg/kg

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC,

NTP or OSHA.

12. Ecological information

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Other adverse effects: No data available

13. Disposal considerations

Local disposal regulations: Dispose in accordance with all applicable regulations.

14. Transport information

This product is Non-hazardous and transport in accordance with local, state regulations. DOT, IMDG, IATA requirements: Not regulated, as material is not considered as Hazardous or Dangerous.

15. Regulatory information

OSHA: Non-hazardous in accordance with international standards for workplace safety.



16. Other information, including date of preparation or last revision

Revision Date: April 05, 2024

Revision No.: 01

Issue date: 04/05/2024

References: Not available.

Granules Pharmaceuticals Inc. believe that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or

implied.

End of Safety Data Sheet