



SAFETY DATA SHEET

Issue Date: 01/15/2023

Revision Date: 06/23/2023

Revision Number: 02

1. IDENTIFICATION

Product identifier: Potassium Chloride Oral Solution, USP 10% and 20%

Product Codes: 0121-4948-15, 0121-1896-30, 0121-0948-16, 0121-4948-94, 0121-4948-40, 0121-4948-50, 0121-4948-80, 0121-4948-00, 0121-1896-40, 0121-1896-50, 0121-1896-00, 0121-2847-15, 0121-2847, 0121-2847-94, 0121-2847-40, 0121-2847-50, 0121-2847-80, 0121-2847-00 and 0121-2847-16.

Supplier Name and Address: Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug – treatment of hypokalemia

Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Potassium Chloride	7447-40-7	10% or 20%
Sodium Citrate Dihydrate	6132-04-3	Proprietary
Citric Acid	77-92-9	Proprietary
Sodium Benzoate	532-32-1	0.05-0.1%
Glycerin	56-81-5	Proprietary
FD&C Yellow No. 6	2783-94-0	Proprietary
Sucralose	56038-13-2	Proprietary
Orange Flavor	Mixture	Proprietary
Water	7732-18-5	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs, get medical attention.

Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

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Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdosage, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing large amounts may cause gastrointestinal irritation, nausea, vomiting, flatulence, abdominal pain and diarrhea. Potassium intoxication causes listlessness, weakness, mental confusion and tingling of the extremities.

Indication of immediate medical attention and special treatment, if necessary: Medical attention is recommended for unintended ingestion or overdosage.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire.

Specific hazards arising from the chemical: Product is not classified as flammable or combustible but will burn in a fire after the water has evaporated.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and collect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid contact with eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging. Protect from light and freezing.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Potassium Citrate Monohydrate	None Established
Sodium Citrate Dihydrate	None Established

Citric Acid	None Established
Sodium Benzoate	2.5 mg/m ³ (inhalable) skin ACGIH TLV
Glycerin	5 mg/m ³ (respirable) 15 mg/m ³ (total dust) TWA OSHA PEL
FD&C Yellow No. 6	None Established
Sucralose	None Established
Orange Flavor	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits and to minimize exposure levels.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None required for normal use. Impervious gloves recommended for manufacturing operations.

Eye protection: None required for normal use. Chemical safety goggles recommended for manufacturing operations.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Clear, orange liquid

Odor: None

Odor threshold: Not applicable	pH: 3.5-4.5
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Evaporation rate: Not determined
Flammability (solid, gas): Not applicable	VOC: Not determined
Flammable limits: LEL: Not determined	UEL: Not determined
Vapor pressure: Not determined	Vapor density: Not determined
Relative density: 1.000-1.2000	Solubility(ies): Soluble
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not determined

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxide, sodium and potassium.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing large amounts may cause gastrointestinal irritation, nausea, vomiting, flatulence, abdominal pain and diarrhea. Potassium intoxication causes listlessness, weakness, mental confusion and tingling of the extremities.

Skin contact: May cause mild irritation.

Eye contact: May cause mild irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens.

Reproductive Toxicity: Components are not classified as reproductive toxins.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, or OSHA.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: >5000 mg/kg

Potassium chloride: Oral mouse LD50 3020 mg/kg

Sodium citrate: Oral rat LD50 5400 mg/kg

Citric Acid: LD50 oral mouse 5400 mg/kg; LD50 dermal rat >2000 mg/kg

Glycerin: LD50 oral rat 12.6 g/kg

12. ECOLOGICAL INFORMATION

Environmental properties have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity values: Potassium chloride: LC50 pimephales promelas 880 mg/L/96h; EC50 daphnia magna 660 mg/L/48h; EC50 scenedesmus subspicatus >100 mg/L/72h.

Sodium citrate: No data available.

Citric acid: EC50 daphnia magna 1535 mg/L/48 hr.; LC50 fish >100-1000 mg/L/96 hr. NOEC algae 425 mg/L

Glycerin: LC50 goldfish >5000 mg/L/24 hr; LC50 daphnia magna >10,000 mg/L/24 hr.

Persistence and degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

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Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

California Proposition 65: This product is not known to contain regulated chemicals.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

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SDS Revision History: N/A

Disclaimer : The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

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SDS Revision History: Added NDC 0121-2847-16 to the product codes.

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