

SAFETY DATA SHEET

Lithium Oral Solution USP, 8 mEq/5 mL

1. IDENTIFICATION

Product identifier: Lithium Oral Solution USP, 8 mEq/5 mL

Product Codes: NDC 0121-1027-16, 0121-4027-05, 0121-4027-94

Supplier Name and Address: PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

Telephone number: (864) 277-7282

Emergency phone number: CHEMTREC 800-424-9300

Recommended use: Human drug

Restrictions on use: Prescription use only

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Eye Irritation Category 2A

Label Elements:

Warning!

Hazard statement(s)

Causes serious eye irritation.



Precautionary statement(s)

Wash hands thoroughly after handling.

Wear eye protection.

IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue

rinsing. If eye irritation persists: Get medical

advice/attention.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Amount
Lithium Carbonate	55401302	1-5%
Citric Acid	77-92-9	7-13%
Sorbitol Solution	50-70-4	Proprietary
Glycerin	56-81-5	Proprietary
Propylene glycol	57-55-6	Proprietary
Methylparaben	99-76-3	Proprietary
Propylparaben	94-13-3	Proprietary
Raspberry Flavor	Mixture	Proprietary

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Water	7732-18-5	Proprietary
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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 or other symptoms occur, get medical attention.

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

Eye contact: Immediately flush eyes with water for 15 minutes while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintentional ingestion or overdose, 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: Causes eye irritation. May cause mild skin irritation. Swallowing may cause effects as seen in clinical use including nausea, fine hand tremor and frequent urination. Symptoms of lithium intoxication include diarrhea, vomiting, drowsiness, dizziness, muscular weakness, and lack of coordination.

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

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.

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.

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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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Lithium Carbonate	None Established
Citric Acid	None Established
Sorbitol Solution	None Established
Glycerin (as mist)	5 mg/m ³ (respirable, 15 mg/m ³ (total) OSHA PEL
Propylene glycol	None Established
Methylparaben	None Established
Propylparaben	None Established
Raspberry 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

Physical State: Liquid	pH: Not determined
Odor: Raspberry	Color: Colorless to slightly colored
Melting point/freezing point: Not determined	Boiling Point: Not determined
Flash point: Not applicable	Particle Characteristics: Not applicable for liquids
Flammability: Not flammable	VOC: Not determined
Flammable limits: LEL: None	UEL: None
Vapor pressure: Same as water	Relative vapor density: Same as water
Relative density: 1.21	Solubility(ies): Partially soluble

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Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Kinematic 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 oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract and possibly symptoms similar to ingestion

Ingestion: Swallowing may cause effects as seen in clinical use including nausea, fine hand tremor and frequent urination. Symptoms of lithium intoxication include diarrhea, vomiting, drowsiness, dizziness, muscular weakness, and lack of coordination.

Skin contact: May cause mild irritation.

Eye contact: Causes serious irritation with redness, pain 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. Lithium hydroxide and lithium hydroxide monohydrate were found to be non-mutagenic in three in vitro tests (AMES tests, Chromosome aberration test, In vitro Mammalian Cell Gene Mutation Test). These can be regarded as reliable prediction for the genotoxic / mutagenic profile of lithium carbonate.

Reproductive Toxicity: Components are not classified as reproductive toxins. Studies in rats, rabbits, and monkeys have shown no evidence of lithium-induced teratology.

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

Lithium Carbonate: Oral rat LD50 525 mg/kg; Inhalation rat LC50 >2 mg/L; Dermal rabbit LD50 >3000 mg/kg

12. ECOLOGICAL INFORMATION

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

Ecotoxicity values: Lithium Carbonate: LC50 fish 137.7 mg/L/96h; EC50 aquatic invertebrates 107 mg/L/48h; EC50 algae 135.1 mg/L. 34-day NOEC fish 15.3 mg/L; 21-day NOEC aquatic invertebrates 5.96 mg/L; NOEC algae 8.8 mg/L.

Persistence and degradability: Biodegradation is not applicable to lithium carbonate as an inorganic compound.

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Bioaccumulative potential: Lithium salts are not bioaccumulative.

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 IMO instruments: Not applicable – product is transported only in packaged form.

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): Refer to Section 2 for the OSHA hazard classification.

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: WARNING: This product can expose you to lithium carbonate, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov

CANADA:

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

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16. OTHER INFORMATION

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SDS Revision History: New SDS

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.