

SAFETY DATA SHEET

Levetiracetam Oral Solution, 100 mg/mL

1. IDENTIFICATION

Product Identifier: Levetiracetam Oral Solution, 100 mg/mL

Synonyms: 1-Pyrrolidineacetamide, alpha-ethyl-2-oxo-, (alphaS)

National Drug Code (NDC): 50383-241-06
50383-241-16

Recommended Use: Pharmaceutical. Levetiracetam Oral Solution is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children one month of age and older with epilepsy.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards: Not classifiable.

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Levetiracetam	1-Pyrrolidineacetamide, alpha-ethyl-2-oxo-, (alphaS)	102767-28-2	C ₈ H ₁₄ N ₂ O ₂	170.21	100 mg/mL

The formula also contains Acesulfame Potassium, Ammonium Glycyrrhizinate, Citric Acid Anhydrous, Glycerin, Maltitol Solution, Methylparaben, Propylparaben, Purified Water, Sodium Citrate Dihydrate and Natural and Artificial Grape Flavor.

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4. FIRST AID MEASURES

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	<p>Commonly reported side effects of Levetiracetam include: infection, psychoneurosis, drowsiness, weakness, nasopharyngitis, nervousness, headache, personality disorder, mental disorders, outbursts of anger, apathy, hyperkinesia, abnormal behavior, hostility, anxiety, depersonalization, depression, agitation, aggressive behavior, fatigue, laceration, irritability, mood changes, and emotional lability.</p> <p>Other side effects include: tonic clonic seizure, dizziness, vertigo, pain, abnormal behavior, influenza, depressed mood, nasopharyngitis, decreased neutrophils, and neck pain.</p>
Medical Conditions Aggravated by Exposure:	Not determined.

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Notes to Physician:

Levetiracetam may cause behavioral abnormalities and psychotic symptoms. Patients treated with Levetiracetam should be monitored for psychiatric signs and symptoms. Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: No data available.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surface to dryness, and then wash with soap and water.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]; excursions permitted to 15° to 30°C (59° to 86°F).

Specific End Use: Pharmaceutical drug product.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Levetiracetam	Not Available	Not Available

Engineering Controls:

Not required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Not required for the normal use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Not required for the normal use of this product. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Not required for the normal use of this product. Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:

Clear, colorless liquid.

Odor:

Grape flavor.

Odor Threshold:

No data available.

pH:

No data available.

Melting Point:

No data available.

Freezing Point:

No data available.

Boiling Point:

No data available.

Flash Point:

No data available.

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Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water; freely soluble in chloroform and methanol; soluble in ethanol; sparingly soluble in acetonitrile and practically insoluble in n-hexane.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Keep away from heat, spark, flames, and other sources of ignition.
Incompatible Materials:	Oxidizing substances.
Hazardous Decomposition Products:	Does not undergo explosive decomposition.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	May cause irritation to the respiratory system.
Ingestion:	Generally safe at recommended doses. Accidental ingestion of large amounts may be harmful.
Skin Contact:	May produce allergic skin reactions.
Eye Contact:	Avoid contact with eyes. May cause eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available.

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Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Levetiracetam	Rat	Oral	LD ₅₀	>5,000 mg/kg
Levetiracetam	Mouse	Oral	LD ₅₀	>5,000 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Doses Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Levetiracetam	Developmental study	Rat	No route specified	1,800 mg/kg/day	No test specified	No fertility impairment observed; increased pup mortality; offspring behavioral changes observed
Levetiracetam	Developmental study	Rabbit	No route specified	600 mg/kg/day	No test specified	Increased embryofetal mortality and fetal skeletal abnormalities
Levetiracetam	Reproductivity study	Rabbit	No route specified	1,800 mg/kg/day	No test specified	Maternal toxicity; increased fetal malformations
Levetiracetam	Reproductivity study	Rat	No route specified	1,800 mg/kg/day	No test specified	No adverse maternal or developmental effects
Levetiracetam	Reproductivity study	Rat	No route specified	350 mg/kg/day	No test specified	Increased skeletal abnormalities and retarded offspring growth

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Levetiracetam	<i>In vitro</i>	Chinese hamster ovary/HPRT locus assay	Negative
Levetiracetam	<i>In vitro</i>	Analysis of metaphase chromosomes from Chinese hamster ovary cells	Negative
Levetiracetam	<i>In vivo</i>	Mouse micronucleus assay	Negative

Aspiration Hazard: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Systemic Effects: No data available.

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Reproductive Effects: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. In animal studies, Levetiracetam produced evidence of developmental toxicity, including teratogenic effects, at doses similar to or greater than human therapeutic doses. Levetiracetam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Carcinogenicity: Rats were dosed with Levetiracetam in the diet for 104 weeks at doses of 50, 300 and 1800 mg/kg/day. The highest dose is 6 times the maximum recommended daily human dose (MRHD) of 3000 mg on a mg/m basis and it also provided systemic exposure (AUC) approximately 6 times that achieved in humans receiving the MRHD. There was no evidence of carcinogenicity. In mice, oral administration of Levetiracetam for 80 weeks (doses up to 960 mg/kg/day) or 2 years (doses up to 4000 mg/kg/day, lowered to 3000 mg/kg/day after 45 weeks due to intolerability) was not associated with an increase in tumors. The highest dose tested in mice for 2 years (3000 mg/kg/day) is approximately 5 times the MRHD on a mg/m basis.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

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14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Levetiracetam	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Levetiracetam	Listed	Listed	Not Listed

California Proposition 65: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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