



SAFETY DATA SHEET

1. Identification

Product identifier **Levetiracetam**

Other means of identification

Catalog number 1359404

Chemical name 1-Pyrrolidineacetamide, alpha-ethyl-2-oxo-, (alphaS)

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300
Canada
CHEMTREC outside US & +1 703-527-3887
Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Specific target organ toxicity, single Category 3 narcotic effects
exposure

OSHA hazard(s) Not classified.

Label elements



Signal word Warning

Hazard statement May cause drowsiness or dizziness.

Precautionary statement

Prevention Use only outdoors or in a well-ventilated area.

Response If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/medical professional.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Levetiracetam		102767-28-2	100

4. First-aid measures

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia. May be dialyzable. (Meditext)
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. 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.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, 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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Faint odor.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	242.6 °F (117 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Very soluble.
Partition coefficient (n-octanol/water)	-0.52
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Pyrrolidinone derivative.
Molecular formula	C8H14N2O2
Molecular weight	170.21
Solubility (other)	Freely soluble in chloroform and in methanol; soluble in ethanol; sparingly soluble in acetonitrile; practically insoluble in n-hexane.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None under normal conditions.
Incompatible materials	None known.
Hazardous decomposition products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Due to lack of data the classification is not possible.
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Inhalation	Due to lack of data the classification is not possible.	
Skin contact	Due to lack of data the classification is not possible.	
Eye contact	Due to lack of data the classification is not possible.	
Symptoms related to the physical, chemical, and toxicological characteristics	Dizziness. Tiredness. Weakness. Drowsiness. Sore mouth or tongue. Infection. Behavior, mood, or mental changes.	
Delayed and immediate effects of exposure	Psychosis. Suicidal thoughts. Coma. Death.	
Medical conditions aggravated by exposure	Impaired kidney function.	
Acute toxicity	Based on available data, the classification criteria are not met.	
Product	Species	Test Results
Levetiracetam (CAS 102767-28-2)		
<i>Oral</i>		
LD50	Mouse	> 5000 mg/kg
	Rat	> 5000 mg/kg
Skin corrosion/irritation	Due to lack of data the classification is not possible.	
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.	
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Due to lack of data the classification is not possible.	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.	
Mutagenicity		
Ames assay		
Result: Negative.		
In vitro Chinese hamster ovary/HGPRT locus assay		
Result: Negative.		
In vitro analysis of metaphase chromosomes from Chinese hamster ovary cells		
Result: Negative.		
In vivo mouse micronucleus assay		
Result: Negative.		
Carcinogenicity	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
1800 mg/kg/day Carcinogenicity study		
Result: There was no evidence of carcinogenicity.		
Species: Rat		
Test Duration: 104 weeks		
Reproductive toxicity	Based on available data, the classification criteria are not met.	
Reproductivity		
1800 mg/kg/day Reproductivity study		
Result: Decreased fetal weights, increased fetal malformations, and maternal toicity occurred.		
Species: Rabbit		
1800 mg/kg/day Reproductivity study		
Result: There was no evidence of developmental or material effects when administered during the last thrid of gestation and throughout lactation.		
Species: Rat		
1800 mg/kg/day Reproductivity study		
Result: There was no evidence of fertility impairment, but increased pup mortality and offsprng behavioral changes occurred.		
Species: Rat		
350 mg/kg/day Reproductivity study		
Result: Increased incidence of minor skeletal abnormalities and retarded offspring growth pre- and/or postnatally occurred in females administered throughout pregnancy and lactation. The developmental no-effect dose was 70 mg/kg/day.		
Species: Rat		

Reproductivity

3600 mg/kg/day Reproductivity study
Result: Fetal weights were decreased, the incidence of fetal skeletal variations was increased, and no material toxicity occurred when administered during organogenesis. The developmental no-effect dose was 1800 mg/kg/day.
Species: Rat
600 mg/kg/day Reproductivity study
Result: Increased embryofetal mortality and increased incidences of minor fetal skeletal abnormalities occurred when administered during organogenesis. The developmental no-effect dose was 200 mg/kg/day.
Species: Rabbit

Specific target organ toxicity - single exposure Narcotic effects.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.
Persistence and degradability No data is available on the degradability of this product.
Bioaccumulative potential Not available.
Mobility in soil Not available.
Other adverse effects Not available.

13. Disposal considerations

Disposal instructions This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

Local disposal regulations Not available.

Hazardous waste code Not regulated.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

Issue date 03-06-2008

Revision date 11-26-2012

Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.