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 & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

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

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: Levetiracetam

Hazardous components:
- Chemical name: Levetiracetam
- Common name and synonyms: 102767-28-2
- CAS number: 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
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.
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

Delayed and immediate effects of exposure

Medical conditions aggravated by exposure
Impaired kidney function.

Acute toxicity Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levetiracetam (CAS 102767-28-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Mouse</td>
<td>&gt; 5000 mg/kg</td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 5000 mg/kg</td>
</tr>
</tbody>
</table>

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 toxicity occurred.
Species: Rabbit
1800 mg/kg/day Reproductivity study Result: There was no evidence of developmental or material effects when administered during the last third 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 offspring 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 orliners 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.

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

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

*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.

Disclaimer

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

Revision Information

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