Material Safety Data Sheet

Levetiracetam

Section 1 – Chemical Product & Company Identification

Common Name: Levetiracetam

Manufacturer: Zhejiang Huahai Pharmaceutical Co Ltd

Address: Xunqiao, Linhai, Zhejiang 317024, China

Company Phone Number: 0086 576 85010288

Emergency Phone Number: 0086 576 85010288

Section 2 –Hazards Identification

Not considered hazardous when handled under normal conditions with good house keeping.

Classification of the substance

According to Regulation (EC) No 1272/2008 (CLP).
Eye Irritation (Category 2)
Skin Irritation (Category 2)
Specific target organ toxicity after exposure (Category 3)

According to European Directive 67/548/EEC as amended.
Irritating to eye, skin and respiratory system.

Label element

GHS pictogram (s)

Signal word Warning

Hazard statement(s)

H315	May cause skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Precautionary statement(s)

P280	Wear protective gloves/protective clothing/eye protection/face protection

Hazard symbol(s)

Xi	Irritant

R phrase(s)

R36	Irritating to eye
R37	Irritating to respiratory system
R38	Irritating to skin.

S phrase(s)
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

Section 3 –Composition, Information on Ingredients

Common Name: Levetiracetam

Formula: $C_8H_{14}N_2O_2$

Synonym: n/f

Chemical Name: (αS) - α-ethyl-2-oxo-1-pyrrolidineacetamide

CAS: 102767-28-2

Chemical Family: Pyrrolidinone derivative

Therapeutic Category: Antiepileptic

Section 4 – First Aid Measures

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. Levetriacetam is readily absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Note to Physicians

Overdose Treatment: Treatment of pyrrolidinone derivative overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. For seizures, administer intravenous benzodiazepines. If seizures recur, consider phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia.
3. Levetiracetam is dialyzable. (Meditext 2008)

Section 5 – Firefighting Measures

Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and material.

Fire and Explosion Hazard: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Fighting Procedures: As with all fires, evacuated personnel to a safe area. Fire fighters should use self-contained breathing equipment and protective clothing.

Section 6 – Accidental Release Measures

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protection clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately-labeled container for disposal. Wash spill site.

Section 7 – Handling and Storage

Handling: Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in a well-closed container.

Section 8 – Exposure Controls, Personal Protection

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eyes: Safety goggles or glasses.

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

Section 9 – Physical and Chemical Properties

Appearance and Odor: White crystalline powder, faint odor.

Solubility: Levetiracetam is freely soluble in water and methanol

Melting point: 115~117°C

Partition Coefficient: n-octanol/water: -0.52

Molecular Formula: $C_8H_{14}N_2O_2$

Molecular Weight: 170.21

Section 10 – Stability and Reactivity

Conditions to Avoid: Avoid exposure to light and heat.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition, material emits toxic fumes of NOx. Emits toxic fumes under fire conditions.

Stable? Yes
Hazardous Polymerization? No

Section 11 – Toxicological Information

Oral Rat: LD50: >5000 mg/kg

Oral Mouse: LD50: >5000 mg/kg

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Irritancy Data: n/f

Other Toxicity Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

Other Carcinogenicity Data: Rats dosed orally with levetiracetam for 104 weeks at 50, 300 and 1800 mg/kg/day showed no evidence of carcinogenicity.

Mutagenicity Data: Levetiracetam was not mutagenic in the Ames test or in mammalian cells in vitro in the Chinese hamster ovary/HGPRT locus assay. It was not clastogenic in an in vitro analysis of metaphase chromosomes obtained from Chinese hamster ovary cells or in an in vivo mouse micronucleus assay.

Reproductive and Developmental Effects: Administration to female rats throughout pregnancy and lactation was associated with increased incidences of minor fetal skeletal abnormalities and retarded offspring growth pre- and/or postnatally at doses ≥350 mg/kg/day and with increased pup mortality and offspring behavioral alterations at a dose of 1800 mg/kg/day. The developmental no-effect dose was 70 mg/kg/day. When pregnant rats were treated during the period of organogenesis, fetal weights were decreased and the incidence of fetal skeletal variations was increased at a dose of 3600 mg/kg/day. 1200 mg/kg/day was a developmental no-effect dose. There was no evidence of maternal toxicity in this study. Treatment of rats during the last third of gestation and throughout lactation produced

no adverse developmental or maternal effects at doses of up to 1800 mg/kg/day. Treatment of pregnant rabbits during the period of organogenesis resulted in increased embryofetal mortality and increased incidences of minor fetal skeletal abnormalities at doses ≥600 mg/kg/day and in decreased fetal weights and increased incidences of fetal malformations at a dose of 1800 mg/kg/day. The developmental no-effect dose was 200 mg/kg/day. Maternal toxicity was also observed at 1800 mg/kg/day.

Section 12 – Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil!

Section 13 – Disposal Consideration

Dispose of by incineration in accordance with applicable international, national, state, and/or local waste disposal regulations.

Section 14 – Transport Information

The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, or ground transport purposes.

Section 15 – Regulatory Information

Labeling according to EEC Directives: Council Directive 67/548 EEC

R phrase:	R36/37/38	Irritating to eyes, respiratory system and skin.
S phrase:	S36/37/39:	Wear suitable protective clothing, gloves and eye/face protection.

Labeling according to CLP-/GHS:

Hazard Statements:	H315/335	May cause skin/respiratory irritation
	H319	Causes serious eye irritation
Safety Statement:	P280	Wear protective gloves/protective clothing/eye protection /face protection.

Section 16 – Other Information

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