Safety Data Sheet

Levetiracetam Injection

Section 1: Chemical Product and Company Identification

Product Name: Levetiracetam Injection
Chemical Name(s): (S)-2-(2-oxopyrrolidin-1-yl) butanamide
Synonym: Not available
CAS Number: 102767-28-2
RTECS #: Not available
Trade Name: *Keppra Injection*
Chemical Formula: $C_8H_{14}N_2O_2$

Contact Information:
X-GEN Pharmaceuticals, Inc.
PO Box 445, Big Flats, NY 14814
Technical Assistance: 607-562-2700
Online Assistance: www.x-gen.us

Emergency phone number:
National Poison Control
1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):

Potential Acute Health Effects: Harmful if swallowed. Harmful if in contact with skin. Harmful by inhalation.

Potential Chronic Health Effects: Not available

Carcinogenic Effects: 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 an mg/basis.

Mutagenic Effects: 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. The hydrolysis product and major human metabolite of Levetiracetam (ucb L057) was not mutagenic in the Ames test or the in vitro mouse lymphoma assay.

Teratogenic Effects: Not available

Developmental Toxicity: Not available

Adverse Effects: Not available

Section 3: Composition and Information on Ingredients

Principle Components:

Name	CAS #	% by Weight
Levetiracetam	102767-28-2	100

Section 4: First Aid Measures

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

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention immediately.

Skin contact: Wash thoroughly with soap and copious amounts of water for at least 15 minutes. Seek medical attention immediately.

Eye contact: Immediately flush eyes with copious amounts of water for at least 15 minutes. If easy to do, remove contact lenses. Seek medical attention immediately.

Ingestion: If swallowed, wash mouth out with water, provided person is conscious. Seek medical attention immediately.

Notes to physician: Seek product package insert for complete information.

Overdose Treatment: Treat overdose symptomatically.

Section 5: Fire Fighting Measures

Flammability of the product: Not available

Combustion Products: Not available

Unusual Fire and Explosion Hazards: Emits toxic fumes of carbon oxides (CO_x) and nitrogen oxides (NO_x).

Extinguishing Media and instruction: Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land
Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.
Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: Normal room ventilation is expected to be adequate for routine handling of the product.

Release to Water: Refer to local water authority; drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Protective equipment: Keep unnecessary personnel away. Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 7: Handling and Storage

Handling: As a general rule, when handling Levetiracetam Injection, avoid all contact and inhalation of mists and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. DO NOT ingest. Wear suitable protective clothing. Use only in accordance with directions.

Storage: Keep container tightly closed. Keep container in a cool, dry, well ventilated area. Protect from light and store at controlled room temperature 25°C (77°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Not available

Section 8: Exposure Controls / Personal Protection

Engineering Controls: Use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: In laboratory, medical or industrial settings: Safety glasses with side shields. Lab coat. Gloves. Respirator. Be sure to use an approved/ certified respirator or equivalent

Respiratory Protection: Under normal use, respirators are not required. If fumes or mist is generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Liquid.
Color: Clear
Molecular Weight: 170.21 g/mole
Taste: Not available
Odor: Odorless
Odor Threshold: Not available
pH: Between 5.0 and 6.0
Melting Point: Not available
Freezing Point: Not available
Boiling Point: Not available
Flash Point: Not available
Evaporation rate: Not available
Solubility: 100% soluble in water.

Flammability: Not available
Upper Flammable Limit: Not available
Lower Flammable Limit: Not available
Vapor Pressure: Not available
Vapor Density: Not available
Relative density: Not available
Dispersion Properties: Not available
Partition Coefficient: Not available
Auto-Ignition Temperature: Not available
Decomposition Temperature: Not available
Viscosity: Not available

Section 10: Stability and Reactivity

Reactivity: Not available

Chemical stability: The product is stable at normal conditions.

Possibility of hazardous reaction: Not available

Conditions to avoid: Excess heat, incompatible materials, moisture.

Incompatible materials: Oxidizing agents.

Hazardous decomposition products: When heated to decomposition, material emits toxic fumes of NO_x, SO_x, and Na_2O.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Not known to occur.

Section 11: Toxicological Information

Routes of exposure: Absorbed via inhalation, ingestion or skin contact.

Symptoms:
Short Term: Handling of this product in its final form presents minimal occupational exposure risk. Common adverse effects can include neuropsychiatric reactions, somnolence and fatigue, serious dermatological reactions, coordination difficulties, withdrawal seizures, hematologic and hepatic abnormalities. **Long Term:** Not available

Reproductive toxicity: No adverse effects on male or female fertility or reproductive performance were observed in rats at oral doses up to 1800 mg/kg/day (6 times the maximum recommended human dose on an mg/m or systemic exposure [AUC] basis).

FDA Pregnancy Category: C

Toxicity to animals:
Oral Rat: LD_{50}: >5 g/kg **Oral Mouse:** LD_{50} >5 g/kg
Intravenous Rat: 1038 mg/kg **Intravenous Mouse:** 1081 mg/kg

Measures of toxicity: Acute Toxicity

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).

Section 12: Ecological Information

Ecotoxicity: Information is not available on the environmental impact of Levetiracetam. Handle in a manner that prevents spills or releases to the environment.

Bioaccumulation potential: Not available

Products of biodegradation: Not available

Toxicity of the products of biodegradation: Not available

Section 13: Disposal Information

Waste classification: Not available

Waste from residues/unused products: Dissolve or mix material with suitable solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber. Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Not regulated
UN Number: Not available
UN Shipping name: Not available
Transport hazard class: Not available
Packing Group: Not available
Environmental hazard: Not available
Transport in bulk: Not available
Special precautions needed with transport: Not available

Section 15: Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory:

Other Regulations: Not available

Other Classifications:
WHMIS (Canada): Not available

DSCL (EEC): Not available

HMIS (U.S.A.):
Health Hazard: 1
Fire Hazard: 0
Reactivity: 0
Personal Protection: E

National Fire Protection Association (U.S.A.):
Health: 2
Flammability: 0
Reactivity: 0

Protective Equipment: Gloves. Lab coat. Safety glasses. Respirator. Be sure to use an approved/certified respirator or equivalent.

Section 16: Other Information

References: Not available
Created: 1/30/2015
Last Updated: 3/27/2015
Prepared & Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.