



SAFETY DATA SHEET

Levetiracetam in Sodium Chloride Injection

1. Identification

Product Identifier: Levetiracetam in Sodium Chloride Injection

Synonyms: 1-Pyrrolidineacetamide, α -ethyl-2-oxo-, (αS)-; (USP)
(-)-(*S*)- α -Ethyl-2-oxo-1-pyrrolidineacetamide (USP)
(2*S*)-2-(2-Oxopyrrolidin-1-yl) butanamide (Ph.Eur)

National Drug Code (NDC):

Strength	Package	NDC Number
500 mg (5 mg/mL)	1 single-use bag	14789-110-08
	10 bags per carton	14789-110-05
1000 mg (10 mg/mL)	1 single-use bag	14789-220-08
	10 bags per carton	14789-220-10
1500 mg (15 mg/mL)	1 single-use bag	14789-330-08
	10 bags per carton	14789-330-15

Recommended Use: Pharmaceutical

Company: Nexus Pharmaceuticals, Inc.
400 Knightsbridge Pkwy
Lincolnshire IL, 60069
USA

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2. Hazard(s) Identification

Physical Hazards: Not available

Health Hazards: Acute toxicity (oral) Category 4

Eye irritation Category 2A

Specific target organ
toxicity – single exposure
(respiratory tract irritation) Category 2



Symbol(s):

Signal Word:

Warning

Hazard Statement(s):

H373 May cause damage to cardiovascular and central nervous systems through prolonged or repeated exposure.

Precautionary Statement(s):

P260 Do not breathe dust/fumes/gas/mist/vapors/spray

P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local/national/international regulations.

Hazards Not Otherwise Classified:

No additional information available

Unknown acute toxicity

Not applicable

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Chemical Formula	Molecular Weight	Percentage	Classification
Levetiracetam	102767-28-2	C ₈ H ₁₄ N ₂ O ₂	170.21	0.5%, 1%, 1.5%	Acute Tox. 4 (Oral), H302, Eye Irrit. 2A, H319
Sodium Chloride	7647-14-5	NaCl	58.44	0.g%	

Inactive Ingredients: Water for Injection.

4. First Aid Measures

Ingestion:

If signs of toxicity occur, seek medical attention.

Eye Contact:

Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

Skin Contact:

Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

Inhalation:

If not breathing, give artificial respiration.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

No anticipated symptoms after inhalation or skin contact from normal handling of this product. Contact with eyes may produce

irritation with redness and tearing. And may be harmful if swallowed.

Medical Conditions

Aggravated by Exposure: Non known

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media (water spray (fog), foam, dry powder, or carbon dioxide as appropriate) for type of surrounding fire.

Unsuitable Extinguishing Media: None

Specific Hazards Arising from the Chemical:

Fire Hazard: None

Special Protective Equipment

Precautions for FireFighters Wear self-contained breathing apparatus and full protective gear.

6. Accidental Release Measures

General Measures: None

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Stop the flow of material, if this is without risk. Collect spill with absorbent material. Clean spill area thoroughly.

Environmental Precautions: Prevent release to sewers and public waters.

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

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Conditions for Safe Storage: Store in a cool dry place away from light.

Including Any incompatibilities: N/A

Specific End Use: Pharmaceuticals

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Levetiracetam	Not applicable

Engineering Controls: Local exhaust and general ventilation must be adequate to meet exposure standards.

Respiratory Protection: Wear NIOSH approved respirator if workplace exposure standards are exceeded.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Hand: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Skin: Wear suitable working clothes.

9. Physical and Chemical Properties

Physical state	Liquid
Appearance	Clear.
Color	Colorless
Odor	Odorless
Odor threshold	No data available
pH	5.5
Melting point	No data available
Freezing point	No data available
Boiling point	No data available
Flash point	No data available
Relative evaporation rate (butyl acetate=1)	No data available
Flammability (solid, gas)	No data available
Vapor pressure	No data available
Relative vapor density at 20 °C	No data available
Relative density	No data available
Solubility	No data available
Log Pow	No data available

Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosion limits	No data available
Explosive properties	No data available
Oxidizing properties	No data available

10. Stability and Reactivity

Reactivity:	No additional information available.
Chemical Stability:	Stable under normal handling and recommended storage conditions.
Possibility of Hazardous Reactions:	Will not occur.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	None
Incompatible Materials:	Not determined.
Hazardous Decomposition Products:	Not determined.

11. Toxicological Information

Acute Toxicity – Oral:	ATE US 500.00 mg/kg body weight
Acute Toxicity – Dermal:	Not classified
Acute Toxicity – Inhalation:	Not classified
Skin Corrosion/irritation:	Not classified; pH 5.5
Respiratory or skin sensitization:	Not classified; pH 5.5
Serious eye damage/irritation:	Not classified; pH 5.5
Germ cell mutagenicity:	Not classified
Specific target organ toxicity (single exposure):	Not classified
Specific target organ toxicity (repeated exposure)	May cause damage to organs through prolonged or repeated exposure.
Reproductive Effects:	Not classified
Carcinogenicity:	Not classified

Aspiration Hazard: Not classified

12. Ecological Information

Ecotoxicity

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects:

Effect on the global warming GWPmix comment	No known effects from this product. No known effects from this product.
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13. Disposal Considerations

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

14. Transport Information

UN Number: Not applicable.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class(es): Not applicable.

Packing Group: Not applicable.

DOT: Not regulated as a hazardous material.

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

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

15. Regulatory Information

US Federal Regulations:

TSCA Inventory	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.
DEA:	Not listed

State Regulations

Massachusetts:	Not listed.
New Jersey:	Not listed.
Pennsylvania:	Not listed.
California Proposition 65:	Not listed.

16. Other Information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H302	Harmful if swallowed
H319	Causes serious eye irritation
H373	May cause damage to organs through prolonged or repeated exposure

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