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Section 1 - Identification


- (a) **Product Identifier:** Levetiracetam Injection
- (b) **Product Code(s):** 70860-602
70860-603
70860-604
- Common/Trade Name:** Keppra® Injection
- Chemical Name:** (-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide
- Chemical Family:** Antiepileptic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Pre-Mix Bag
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **US OSHA GHS Classification of substance or mixture:**
- Physical Hazards:**
Not Classified
- Health Hazards:**
Hazard Class – STOT-RE
Hazard Category - 2

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

GHS Signal Word:	Warning
GHS Hazard Statement:	May cause damage to organs through prolonged or repeated exposure
GHS Symbols:	

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GHS Precautionary Statements:	<p>Prevention: Do not breathe vapor or spray. Wash hands thoroughly after handling</p> <p>Response: Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.</p>
Other Hazards	N/A

(d) **Unknown Acute Toxicity** N/A


Section 3 – Composition / Information on Ingredients

Levetiracetam in 0.82 % Sodium Chloride Injection, 5 mg/mL

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide	Levetiracetam USP	500.0 mg*	102767-28-2	N/A
Sodium Chloride USP	Sodium Chloride	820.0 mg	7647-14-5	N/A
Glacial Acetic Acid USP	Glacial Acetic Acid	5.5 mg and additional q.s. to adjust pH to 5.5	64-19-7	N/A
Sodium acetate trihydrate USP	Sodium acetate	164.0 mg	6131-90-4	N/A
Water for Injection USP	Water	q.s. to 100 mL	7732-18-5	N/A
Nitrogen NF	Nitrogen	As required	7727-37-9	N/A

*Assay correction required on as is basis.

q.s. – Quantity Sufficient


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Levetiracetam in 0.75% Sodium Chloride Injection, 10 mg/mL

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide	Levetiracetam USP	1000.0 mg*	102767-28-2	N/A
Sodium Chloride USP	Sodium Chloride	750.0 mg	7647-14-5	N/A
Glacial Acetic Acid USP	Glacial Acetic Acid	6.5 mg and additional q.s. to adjust pH to 5.5	64-19-7	N/A
Sodium acetate trihydrate USP	Sodium acetate	164.0 mg	6131-90-4	N/A
Water for Injection USP	Water	q.s. to 100 mL	7732-18-5	N/A
Nitrogen NF	Nitrogen	As required	7727-37-9	N/A

*Assay correction required on as is basis.

q.s. – Quantity Sufficient

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Levetiracetam in 0.54% Sodium Chloride Injection, 15 mg/mL


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide	Levetiracetam USP	1500.0 mg*	102767-28-2	N/A
Sodium Chloride USP	Sodium Chloride	540.0 mg	7647-14-5	N/A
Glacial Acetic Acid USP	Glacial Acetic Acid	7.5 mg and additional q.s. to adjust pH to 5.5	64-19-7	N/A
Sodium acetate trihydrate USP	Sodium acetate	164.0 mg	6131-90-4	N/A
Water for Injection USP	Water	q.s. to 100 mL	7732-18-5	N/A
Nitrogen NF	Nitrogen	As required	7727-37-9	N/A

*Assay correction required on as is basis.

q.s. – Quantity Sufficient

Section 4 – First Aid Measures

- Eye Exposure:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
- Skin Exposure:** The risk of skin contact is negligible when the product is in its final packaged form. If skin contact occurs, wash skin with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, and flush exposed area with large amounts of water. Seek medical attention if skin reaction occurs.
- Ingestion:** Flush mouth out with water and get medical attention.
- Injection:** In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
- Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

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Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures


- (a) **Extinguishing Media** No expected fire or explosion hazard for the final dose product. Extinguish with carbon dioxide, dry chemical powder or appropriate foam. Water spray.
- (b) **Hazardous Combustion Products:** Under fire conditions, may emit fumes of carbon oxides (COx) and nitrogen oxides (NOx).
- (c) **Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

Section 6 - Accidental Release Measures

- Spill:** Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pickup is complete.
- 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.

Section 7 - Handling and Storage

- General Handling:** Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment (PPE) when handling.
- Storage Conditions:** Store at 20 ° to 25 ° C (68 ° to 77 ° F) [see USP Controlled Room Temperature].

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Levetiracetam	OSHA	PEL	NE
	ACGIH	TLV	NE
	AIHA	WEEL	NE

Notes:


OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level

(b) Engineering Controls

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

(c) Individual Protection Measures

Respiratory Protection:	Not generally required when handling product in its final packaged form. In an occupational setting, site-specific risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.
Eye Protection:	Not generally required when handling product in its final packaged form. In laboratory, medical or industrial settings, safety glasses with side shields are recommended if eye contact is possible.
Skin Protection:	Not generally required when handling product in its final packaged form. In laboratory, medical or industrial settings, nitrile or neoprene gloves and lab coats are recommended if contact is possible.
Other Protective Equipment:	None established.
Additional Exposure Precautions:	None established.


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Section 9 - Physical and Chemical Properties

(a) Appearance	clear, colorless, sterile solution
(b) Odor	Not available
(c) Odor Threshold	Not available
(d) pH	5.5
(e) Melting Point:	Not available
(f) Initial Boiling Point:	Not available
(g) Flash Point	Not available
(h) Evaporation Rate:	Not available
(i) Flammability	Not available
(j) Upper Lower Flammability or Explosion Limits	Not available
(k) Vapor Pressure:	Not available
(l) Vapor Density:	Not available
(m) Relative Density	Not available
(n) Solubility(ies)	Not applicable
(o) Partition Coefficient: n-octanol/water	Not available
(p) Auto-ignition Temperature	Not available
(q) Decomposition Temperature	Not available
(r) Viscosity	Not available

Section 10 - Stability and Reactivity

(a) Reactivity	Not determined
(b) Chemical Stability	Stable under standard use and storage conditions.
(c) Possibility of Hazardous Reactions	Hazardous polymerization not anticipated to occur with this product.
(d) Conditions to Avoid	Extreme heat, cold or moisture.
(e) Incompatible Materials	Keep away from strong oxidizers.
(f) Hazardous Decomposition Products	Not established. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x) and nitrogen oxides (NO _x).

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Product may be absorbed via inhalation, ingestion or skin contact.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	This drug is intended for therapeutic use only when prescribed by a physician. In patients being treated with levetiracetam, psychiatric reactions, somnolence and fatigue, serious dermatological reactions, coordination difficulties, withdrawal seizures and hematologic abnormalities can occur. Please refer to the product information insert or product label for more detailed information.
(c)	Delayed and immediate effects and chronic effects from short and long-term exposure	Handling of this product in its final form presents minimal occupational exposure risk. Common adverse effects can include psychiatric reactions, somnolence and fatigue, serious dermatological reactions, coordination difficulties, withdrawal seizures and hematologic abnormalities. For full detailed list of adverse effects refer to product information insert.

(d) Acute Toxicity


Component	Type	Route	Species	Dosage
Levetiracetam	LD ₅₀	Intravenous	Rat	1038 mg/kg
	LD ₅₀	Intravenous	Mouse	1081 mg/kg
	LD ₅₀	Oral	Rat	>5 g/kg
	LD ₅₀	Oral	Mouse	>5 g/kg
Sodium Chloride	LD ₅₀	Oral	Rat	3 g/kg
	LD ₅₀	Dermal	Rabbit	>10 g/kg
	LD ₅₀ , 1 hour	Inhalation	Rat	>42 g/m ³
Water	LD ₅₀	Oral	Rat	>90 mL/kg

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

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Section 12 - Ecological Information

(a)	Ecotoxicity	<p>Water flea (<i>Daphnia magna</i>) – EC50 48 h: 340.7 – 469.2 mg/L Static</p> <p><u>Fish</u> <i>Oncorhynchus mykiss</i> – LC50 96h: 4747-7824 mg/L flow-through <i>Lepomis macrochirus</i> – LC50 96h: 5560-6080 mg/L flow-through <i>Pimephales promelas</i> – LC50 96h: 6020-7070 mg/L static <i>Pimephales promelas</i> – LC50 96h: 6420-6700 mg/L static <i>Lepomis macrochirus</i> – LC50 96h: 12946 mg/L static <i>Pimephales promelas</i> – LC50 96h: 7050 mg/L semi-static</p>
(b)	Persistence and degradability	No applicable ecological information found.
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

- TSCA – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 311/312: Not on this list
- SARA 313 - Not on this list
- OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances

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ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS024

Revision: 01

Title: Levetiracetam Injection

All dates and times are in Eastern Standard Time.

SDS Approval

Change Request

Name/Signature	Title	Date	Meaning/Reason
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Quality	11 Jun 2018, 04:26:28 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	12 Jun 2018, 09:55:27 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	12 Jun 2018, 10:09:19 AM	Approved