

### 1 PRODUCT AND COMPANY INFORMATION

<b>Product Name:</b>	<b>Levetiracetam in Sodium Chloride Injection</b>
<b>Other means of identification – Synonyms</b>	(-)-(S)- $\alpha$ -ethyl-2-oxo-1-pyrrolidine acetamide
<b>Distributed By:</b>	WG Critical Care, LLC 120 Route 17 North Suite 115 Paramus, NJ 07652 USA
<b>Customer Service Phone Number:</b>	1-888-493-0861
<b>Emergency Phone Number:</b>	1-866-562-4708 (ProPharma)
<b>Recommended Use</b>	Pharmaceuticals product used as antiepileptic agent, for electrolyte replacement
<b>Uses advised against</b>	This is a pharmaceutical product designed to be administered by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
<b>Container Information:</b>	Plastic Bags

### 2 HAZARDS IDENTIFICATION

This product is intended for therapeutic use only when prescribed by a Health Care professional. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Classification	Contains: Levetiracetam	
Health Hazards		
Physical hazards	Hazard Class	Hazard Category
GHS	STOT Repeated exposure	Category 1 (Oral, Nervous System)
	Reproductive toxicity	Category 2
	Skin Sensitization	Category 1
	STOT Single Exposure	Category 3
EU	Not classified	Not classified

Emergency Overview  
 Contains: Levetiracetam



Labels element:  
 Signal Word: Warning

**Hazard Statement**

H302: Harmful if swallowed.  
 H319: Causes serious eye irritation  
 P264: Wash {hands} thoroughly after handling.  
 P280: Wear {protective gloves/protective clothing/eye protection/face protection}

**Precautionary Statements – Prevention**

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### Precautionary Statements – Response

P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.  
 P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P330: Rinse mouth.  
 P337+313: If eye irritation persists, get medical advice/attention

### Precautionary Statements - Storage

Store at 20 – 25 °C (68 - 77°F).

### Precautionary Statements - Disposal

Dispose of waste in accordance with all applicable laws and regulations

**Overview: The product is intended for therapeutic use only when prescribed by a health care professional. Potential adverse reaction from prescribed doses and overdoses are described in the package insert.**

## 3 COMPOSITION / INFORMATION ON INGREDIENTS

Common name		Levetiracetam Injection 5mg/mL	
Chemical Name	CAS No.		Amount mg/mL
Levetiracetam	102767-28-2		5.0
Sodium Chloride	7647-14-5		8.2
Glacial Acetic Acid	64-19-7		0.055
Sodium Acetate Trihydrate	6131-90-4		1.64
Water for Injection	7732-18-5		q.s. to ~ 1 mL

Common name		Levetiracetam Injection 10mg/mL	
Chemical Name	CAS No.		Amount mg/mL
Levetiracetam	102767-28-2		10.0
Sodium Chloride	7647-14-5		7.5
Glacial Acetic Acid	64-19-7		0.065
Sodium Acetate Trihydrate	6131-90-4		1.64
Water for Injection	7732-18-5		q.s. to ~ 1 mL

Common name		Levetiracetam Injection 15mg/mL	
Chemical Name	CAS No.		Amount mg/mL
Levetiracetam	102767-28-2		15.0
Sodium Chloride	7647-14-5		5.4
Glacial Acetic Acid	64-19-7		0.075
Sodium Acetate Trihydrate	6131-90-4		1.64
Water for Injection	7732-18-5		q.s. to ~ 1 mL

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### 4 FIRST AID MEASURES

<b>First aid measures</b>	
<b>General advice</b>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<b>In case of Inhalation</b>	Remove to fresh air and keep patient at rest. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek medical attention immediately.
<b>In case of Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>In case of Eye Contact</b>	Remove from source of exposure. If easy to do, remove contact lenses. Flush with plenty of water and seek medical advice.
<b>In case of Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Self-protection of the first aider</b>	Avoid contact with eyes and wear personal protective equipment.

Most important symptoms and effects, both acute and delayed

Symptoms and Effects of Exposure: No data available

Note to physicians - See patient package insert in shipping carton for complete information.

### 5 FIRE FIGHTING MEASURES

**Suitable extinguishing media**

No expected fire or explosion hazard for the final dose product. Use alcohol resistant foam, carbon dioxide, dry chemical or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and surrounding environment.

A solid water stream may be inefficient

**Unsuitable extinguishing media**

**Specific hazards arising from the chemical**

**Hazardous combustion products**

Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Not applicable

**Sensitivity to Mechanical Impact**

**Protective equipment and precautions for firefighters**

During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

### 6 ACCIDENTAL RELEASE MEASURE

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions**

Evacuate and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mist. Use proper personal protective equipment as listed in Section 8.

**Environmental precautions**

Take step to avoid release into the environment if safe to do so. Avoid runoff into storm sewers, ditches and waterways. See Section 12 for additional ecological information.

**Methods and material for containment and cleaning up**

**Methods for containment**

Prevent further leakage or spillage if safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Methods for cleaning up**

Absorb spill with inert material, then place in a chemical waste container for disposal in accordance with local, state, and national regulations. After removal, flush spill area with soap and water to remove trace residue.

### 7 HANDLING AND STORAGE

**Precautions for safe handling**

**Advice on safe handling** - Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** - Store at 20-25°C. See package insert

**Incompatible materials** - Not applicable

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### 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters:**

**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	AIHA WEEL
Levetiracetam	8hr TWA: Not Established	8hr TWA: Not Established	8hr TWA: Not Established

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

**Appropriate engineering controls**

**Engineering Controls**

General ventilation is sufficient if this product is being used in a controlled medical setting (clinical, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

Not generally required when handling product in its final packaged form. In laboratory, medical or industrial setting, safety glasses with side shields are recommended if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin and body protection**

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. Wear appropriate protective gloves. Nitrile rubber or natural rubber gloves are recommended. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent).

**Respiratory protection**

No personal respiratory protective equipment is normally required when this product is being used, administered by licensed healthcare practitioner for its sole intended parenteral purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/nppti/topics/respirators/>) for a list of respirator types and approved suppliers. Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

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**General Considerations**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment.

### 9 PHYSICAL AND CHEMICAL PROPERTIES

<b>PHYSICAL STATE:</b>	Liquid	<b>APPEARANCE:</b>	Clear colorless solution
<b>UPPER FLAMMABILITY LIMIT:</b>	No data available	<b>LOWER FLAMMABILITY LIMIT:</b>	No data available
<b>EXPLOSIVE LIMITS:</b>	No data available	<b>ODOR:</b>	Faint odor
<b>VAPOR PRESSURE:</b>	No data available	<b>ODOR THRESHOLD:</b>	No data available
<b>VAPOR DENSITY:</b>	No data available	<b>pH:</b>	5.5
<b>RELATIVE DENSITY:</b>	No data available	<b>MELTING POINT:</b>	No data available
<b>FREEZING POINT:</b>	No data available	<b>SOLUBILITY IN WATER:</b>	No data available
<b>INITIAL BOILING POINT:</b>	No data available	<b>BOILING RANGE:</b>	No data available
<b>FLASH POINT:</b>	No data available	<b>EVAPORATION RATE:</b>	No data available
<b>FLAMMABILITY:</b>	No data available	<b>PARTITION COEFFICIENT (N-OCTANOL / WATER)</b>	1.89
<b>AUTO-IGNITION TEMPERATURE:</b>	No data available	<b>DECOMPOSITION TEMPERATURE:</b>	No data available
<b>VISCOSITY:</b>	No data available	<b>SOLUBILITY IN OTHER SOLVENTS</b>	No data available
<b>SPECIFIC GRAVITY:</b>	0.6	<b>MOLECULAR WEIGHT:</b>	N/A

### 10 STABILITY AND REACTIVITY

<b>Reactivity:</b>	Not determined
<b>Chemical Stability:</b>	Stable under normal conditions of use
<b>Possibility of Hazardous reactions/polymerization:</b>	Not anticipated to occur with this product
<b>Conditions to avoid:</b>	Excessive heat, cold or moisture Fine particles (such as dust and mists) may fuel/explosions
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous decomposition products:</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen fluoride.

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### 11 TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

##### Product Information

The information included in this section describes the potential hazards of the individual ingredients.

Product may be adsorbed via inhalation, ingestion or skin contact.

#### Acute toxicity

Chemical Name - Levetiracetam

Oral Tox Data LD50 - Rat > 5,000 mg/kg and Mouse > 5,000mg/kg

Dermal LD50 – N/A

Inhalation LC50 – N/A

Intravenous Tox Data - Rat 1,038 mg/kg and Mouse 1,081 mg/kg

Chemical Name - Sodium Chloride

Oral Tox Data LD50 - Rat 3,000 mg/kg and Mouse 4,000 mg/kg

Dermal LD50 – Rabbit > 10g/kg

Inhalation LC50 - Rat > 42 g/kg

Intravenous Tox Data – N/A

Irritation toxicity - Sodium Chloride

Eye Irritation - Rabbit - Mild

Skin Irritation - Rabbit – Mild

#### Information on toxicological effects

##### Symptoms

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.

#### Delayed and immediate effects as well as 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.

#### Germ cell mutagenicity

- In Vitro Bacterial Mutagenicity (Ames) Salmonella Negative
- In Vitro HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
- In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
- In Vivo Micronucleus Mouse Negative

#### Carcinogenicity

**Carcinogenic Status:** None of the components of this formulation are listed as a carcinogen by IAR, NTP or OSHA

#### Levetiracetam

Duration: 80 Weeks Species: Mouse – Route: Oral Dose: not specified \_ Effect: Not carcinogenic

Duration: 104 Weeks - Species: Rat - Route: Oral Dose: 1800mg/kg/day \_ End Point: NOAEL Not carcinogenic

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### Reproduction & Developmental Toxicity

- Embryo / Fetal Development Rat Oral 70 mg/kg/day NOEL Fetotoxicity, Embryotoxicity
- Embryo / Fetal Development Rabbit Oral 200 mg/kg/day NOAEL Embryotoxicity, Fetotoxicity, Maternal Toxicity
- Peri/Postnatal Development Rat Oral Dose not specified No effects at maximum dose

### Repeat Dose Toxicity

Duration: 6 month (s) Species: Rat Route: Oral  
 Dose: >=50 mg/kg/day Endpoint: LOAEL Target organ: Liver, Kidney, Central nervous system

## 12 ECOLOGICAL INFORMATION

### Toxicity

**Environment Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

#### AQUATIC TOXICITY:

- Oncorhynchus mykiss* – LC50 96h: 4747-7824 mg/L flow-through
- Lepomis macrochirus* – LC50 96h: 5560-6080 mg/L flow-through
- Pimephales promelas* – LC50 96h: 6020-7070 mg/L static
- Pimephales promelas* – LC50 96h: 6420-6700 mg/L static
- Lepomis macrochirus* – LC50 96h: 12946 mg/L static
- Pimephales promelas* – LC50 96h: 7050 mg/L semi-static

#### PERSISTENCE AND DEGRADABILITY:

Not determined for product.

#### BIOACCUMULATION:

Not determined for product.

#### OTHER ADVERSE EFFECTS:

No data available

## 13 DISPOSAL CONSIDERATIONS

### Waste treatment methods

#### Disposal of wastes

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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<b>Contaminated packaging</b>	Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse the container.
<b>US EPA Waste Number</b>	Not applicable
<b>California Hazardous Waste Codes</b>	Not applicable

### 14 TRANSPORT INFORMATION

<b>DOT</b>	not regulated
<b>ICAO (air)</b>	not regulated
<b>IATA</b>	not regulated
<b>IMDG</b>	not regulated
<b>RID</b>	not regulated
<b>ADR</b>	not regulated
<b>ADG</b>	not regulated
<b>Special precautions</b>	none

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### 15 REGULATORY INFORMATION

Levetiracetam	
CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Standard for the Uniform Scheduling for Drugs and Poisons	Schedule 4
EU EINECS/ELINCS List	Not listed
Sodium Chloride	
CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
Sodium acetate trihydrate	
CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not listed
Glacial acetic acid USP	
CERCLA/SARA 313 Emission reporting	Not listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities	5000 lb 2270 kg
California Proposition 65	Not listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drug and Poisons	Schedule 2/ Schedule 5/ Schedule 6
EU EINECS/ELINCS List	200-580-7

### 16 OTHER INFORMATION

As of the date of issuance, 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 MATERIAL 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.

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