

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations
Date of Issue: 05/22/2025

Version: 1.0

# **SECTION 1: IDENTIFICATION**

1.1. Product Identifier
Product Form: Mixture

Product Name: Levetiracetam in Sodium Chloride Injection1.2 Recommended Use and Restrictions on Use

**Use Of The Substance/Mixture** : Anti-epileptic agent for electrolyte replacement

**Restrictions On Use** : No additional information available

#### 1.3. Name, Address, and Telephone of the Responsible Party

Company

WG Critical Care, LLC

120 Route 17 North, Suite 115 Paramus, NJ 07652 USA

+ 1-888-493-0861

wgccquality@wgcriticalcare.com https://www.wgcriticalcare.com/

# 1.4. Emergency Telephone Number

**Emergency Number** : +1-866-562-4708 (ProPharma)

#### **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the Substance or Mixture

#### **GHS-US Classification**

Reproductive toxicity, Category 2 H361
Reproductive toxicity, Additional category, Effects on or via lactation H362
Specific target organ toxicity – Single exposure, Category 3, Narcosis H336

#### 2.2. Label Elements

# **GHS-US Labeling**

Hazard Pictograms (GHS-US)

**Precautionary Statements (GHS-US)** 





Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H336 - May cause drowsiness or dizziness.

H361 - Suspected of damaging fertility or the unborn child (oral).

H362 - May cause harm to breast-fed children.P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe mist, spray, or vapors.

P263 - Avoid contact during pregnancy and while nursing.

P264 - Wash hands, forearms and face thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear eye protection, protective gloves and clothing.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position

comfortable for breathing.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P312 - Call a poison center or doctor if you feel unwell.

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

P405 - Store locked up.

P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

# 2.3 Hazards associated with known or reasonably anticipated uses

This product is a pharmaceutical product designed for administration to a patient by a qualified medical professional. No other uses are anticipated. If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

05/22/2025 EN (English US) 1/7

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

#### 2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

# 2.5. Unknown Acute Toxicity (GHS-US)

No data available

# **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Synonyms	Product Identifier	<b>%</b> *	GHS US classification
Water	AQUA	(CAS-No.) 7732-18-5	80 – 100	Not classified.
Levetiracetam	(2S)-2-(2-Oxopyrrolidine-1-yl)butaneamide	(CAS-No.) 102767-28-2	0.5 – 2.0	Repr. 2, H361 Lact., H362 STOT SE 3, H336
Sodium acetate trihydrate	Acetate, sodium, trihydrate / Acetic acid, sodium salt, trihydrate / Sodium acetate-3-hydrate / Acetic acid, sodium salt, hydrate (1:1:3) / Sodium acetate	(CAS-No.) 6131-90-4	0.1 – 1	Combustible Dust
Sodium chloride	Sea salt / Sodium chloride (NaCl) / SODIUM CHLORIDE / Sodium salt of hydrochloric acid / Salt / SEA SALT	(CAS-No.) 7647-14-5	0.1 – 1	Not classified.
Acetic acid	Acetic acid, glacial / Ethanoic acid / Ethylic acid / Vinegar acid / ACETIC ACID / Acetic acid solution / Acetic acid% / Acetic acid %	(CAS-No.) 64-19-7	<0.1	Flam. Liq. 3, H226 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

<sup>\* -</sup> The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the OSHA Hazard Communication Standard 29 CFR 1910.1200. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-phrases: see section 16.

# **SECTION 4: FIRST AID MEASURES**

#### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Immediately remove contaminated clothing. Drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

**First-aid Measures After Eye Contact:** Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists. Rinse cautiously with water for at least 15 minutes.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

# 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** May cause drowsiness and dizziness. Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

**Symptoms/Injuries After Inhalation:** High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headache, and similar narcotic symptoms.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

# 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Accidental injections should be treated as a medical emergency. Treat symptomatically.

05/22/2025 EN (English US) 2/7

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

# **SECTION 5: FIRE-FIGHTING MEASURES**

# 5.1. Extinguishing Media

Suitable Extinguishing Media: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Product is not flammable. **Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire. **Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Oxides of carbon, nitrogen, sodium, and chlorine compounds.

Other Information: No additional information available.

### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

# 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

#### 6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

# 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

#### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

# 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. **Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

#### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

# **SECTION 7: HANDLING AND STORAGE**

# 7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use. Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist, or spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols.

**Handling Temperature:** See Section 7.2, Storage, for suggested temperature range.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers. **Storage Temperature:** 20 – 25 °C (68 – 77 °F). DO NOT FREEZE!

# 7.3. Specific End Use(s)

Anti-epileptic agent for electrolyte replacement

05/22/2025 EN (English US) 3/7

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. **Control Parameters**

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Acetic acid (64-19-7)		
USA ACGIH	ACGIH OEL TWA	10 ppm
USA ACGIH	ACGIH OEL STEL	15 ppm
<b>USA NIOSH</b>	NIOSH REL TWA	25 mg/m <sup>3</sup>
<b>USA NIOSH</b>	NIOSH REL TWA	10 ppm
<b>USA NIOSH</b>	NIOSH REL STEL	37 mg/m <sup>3</sup>
<b>USA NIOSH</b>	NIOSH REL STEL	15 ppm
USA IDLH	IDLH	50 ppm
USA OSHA	OSHA PEL TWA	25 mg/m <sup>3</sup>
USA OSHA	OSHA PEL TWA	10 ppm

# **Exposure Controls**

**Appropriate Engineering Controls** : Suitable eye/body wash equipment should be available in the vicinity of any

potential exposure. Ensure adequate ventilation, especially in confined areas.

Ensure all national/local regulations are observed.

: Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: **Personal Protective Equipment** wear respiratory protection.









**Materials for Protective Clothing** 

**Hand Protection** : Wear protective gloves.

**Eye and Face Protection** : Chemical goggles or face shield. **Skin and Body Protection** : Wear suitable protective clothing.

**Respiratory Protection** : If exposure limits are exceeded or irritation is experienced, approved respiratory

protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory

protection.

**Thermal Hazard Protection** : Not applicable.

**Environmental Exposure Controls** : Avoid unnecessary release into the environment.

Other Information : When using, do not eat, drink or smoke.

# **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

#### 9.1. **Information on Basic Physical and Chemical Properties**

**Physical State** 

Color : Clear, colorless liquid solution

Odor : No data available

: 5.5 pН

**Melting Point** : No data available **Freezing Point** : No data available **Boiling Point** No data available **Flash Point** : No data available **Auto-ignition Temperature** : No data available **Decomposition Temperature** : No data available Flammability (solid, gas) : Not applicable **Vapor Pressure** No data available Relative Vapor Density at 20°C : No data available **Relative Density** : No data available

Density : ≈ 1.012 g/ml

Solubility : Water: Soluble/miscible

**Partition Coefficient: N-Octanol/Water** : No data available Viscosity, Kinematic : No data available **Particle characteristics** : No data available

05/22/2025 EN (English US)

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

### 9.2. Other Information

No additional information available

# **SECTION 10: STABILITY AND REACTIVITY**

# 10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

#### 10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

#### 10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies

Hazardous polymerization will not occur.

#### 10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

#### 10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

#### 10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Oxides of carbon, nitrogen, sodium, and chlorine compounds.

# **SECTION 11: TOXICOLOGICAL INFORMATION**

# 11.1. Information on Toxicological Effects

Likely Routes of Exposure: Dermal, Ingestion, Inhalation, Eye contact

Acute Toxicity (Oral): Not classified.
Acute Toxicity (Dermal): Not classified.
Acute Toxicity (Inhalation): Not classified.

Levetiracetam (102767-28-2)		
LD50 Oral Rat	> 5000 mg/kg	
Sodium chloride (7647-14-5)		
LD50 Oral Rat	3550 mg/kg (Species: Wistar)	
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)	
LC50 Inhalation Rat	> 42 mg/l (Exposure time: 1 h Source: ECHA_API)	
Acetic acid (64-19-7)		
LD50 Oral Rat	3310 mg/kg (Source: JAPAN_GHS)	
LD50 Dermal Rabbit	1060 mg/kg (Source: JAPAN_GHS)	
LC50 Inhalation Rat	11.4 mg/l/4h	
Water (7732-18-5)		
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)	

Skin Corrosion/Irritation: Not classified.

**pH:** 5.5

Serious Eye Damage/Irritation: Not classified.

**pH:** 5.5

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

**Reproductive Toxicity:** Suspected of damaging fertility or the unborn child (oral). May cause harm to breast-fed children. (This material or its emissions may appear in breast milk of nursing mothers.)

Specific Target Organ Toxicity (Single Exposure): May cause drowsiness or dizziness.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: High concentrations may cause central nervous system depression such as dizziness,

vomiting, numbness, drowsiness, headache, and similar narcotic symptoms.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Chronic Symptoms: Suspected of damaging fertility or the unborn child.

# **SECTION 12: ECOLOGICAL INFORMATION**

### 12.1. Toxicity

**Ecology - General** : Not classified.

05/22/2025 EN (English US) 5/7

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

Sodium chloride (7647-14-5)		
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-	
	through])	
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)	
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)	
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])	
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)	
Acetic acid (64-19-7)		
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static] Source: EPA)	
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])	
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static] Source: EPA)	

#### 12.2. Persistence and Degradability

Levetiracetam in Sodium Chloride Injection	
Persistence and Degradability	Expected to be biodegradable.

#### 12.3. Bioaccumulative Potential

Levetiracetam in Sodium Chloride Injection		
Bioaccumulative Potential	Not expected to bioaccumulate.	
Sodium chloride (7647-14-5)		
BCF Fish 1	(no bioaccumulation)	
Acetic acid (64-19-7)		
Partition coefficient n-octanol/water (Log	-0.17 (at 25 °C (at pH 7)	
Pow)		

#### 12.4. Mobility in Soil

Levetiracetam in Sodium Chloride Injection	
Ecology - Soil	Adsorbs into the soil. Leaches if exposed to water.

#### 12.5. Other Adverse Effects

Other Adverse Effects : None known.

**Other Information** : Avoid release to the environment.

#### **SECTION 13: DISPOSAL CONSIDERATIONS**

#### 13.1. Waste Treatment Methods

**Waste Treatment Methods:** Incineration is the preferred method for disposal of waste product. Can be landfilled, when in compliance with local regulations.

**Sewage Disposal Recommendations:** Do not dispose of waste into sewer. Do not empty into drains.

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Biologically contaminated materials should be incinerated. **Ecology - Waste Materials:** Avoid unnecessary release into the environment.

# **SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

# 14.1. In Accordance with DOT

Not regulated for transport

#### 14.2. In Accordance with IMDG

Not regulated for transport

# 14.3. In Accordance with IATA

Not regulated for transport

# **SECTION 15: REGULATORY INFORMATION**

### 15.1. US Federal Regulations

Levetiracetam in Sodium Chloride Injection		
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated	
	exposure)	
	Health hazard - Reproductive toxicity	

05/22/2025 EN (English US) 6/7

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

Sodium chloride (7647-14-5)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active		
Acetic acid (64-19-7)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active		
CERCLA RQ 5000 lb		
Water (7732-18-5)		

#### Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active 15.2. **US State Regulations**

#### Acetic acid (64-19-7)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

# SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest Revision** : 05/22/2025

Other Information This document has been prepared in accordance with the SDS

requirements of the OSHA Hazard Communication Standard 29 CFR

1910.1200

#### **GHS Full Text Phrases:**

H226	Flammable liquid and vapor
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H336	May cause drowsiness or dizziness
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H402	Harmful to aquatic life

### **Glossary of Data Source Abbreviations**

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of

Health and Human Services) AU\_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency) EC\_RAR: European Commission Renewal Assessment Report

EC\_SCOEL: European Commission Scientific Committee on Occupational

**Exposure Limits** 

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals

Reports

ECHA\_API: European Chemicals Agency API ECHA\_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority EPA: U.S. Environmental Protection Agency

EPA\_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection

Agency)

EPA\_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration

Fligibility Decision (U.S. Environmental Protection Agency)

EPA HPV: High Production Volume Chemicals (U.S. Environmental Protection

Agency) EPA\_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision

(U.S. Environmental Protection Agency)

EU\_CLH: European Union Harmonised Classification and Labelling Proposal

EU RAR: European Union Risk Assessment Report

FOOD\_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately

Dangerous to Life or Health Value Profiles

**IUCLID:** International Uniform Chemical Information Database

JAPAN\_GHS: Japan GHS Basis for Classification Data

JP J-CHECK: Japan J-Check

KR\_NIER: South Korea National Institute of Environmental Research

**Evaluations** 

NICNAS: Australia National Industrial Chemicals Notification and Assessment

Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S.

Department of Health and Human Services)

NLM\_CIP: National Library of Medicine ChemID plus database

NLM\_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ CCID: New Zealand Chemical Classification and Information Database OECD\_EHSP: Environment, Health, and Safety Publication (Organisation for

**Economic Co-operation and Development)** 

OECD\_SIDS: Screening Information Data Sets (Organisation for Economic Co-

operation and Development) WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and

SDS US (GHS HazCom)

05/22/2025 EN (English US) 7/7

environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.