

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name : Levetiracetam in 0.82% Sodium Chloride Injection 500 mg/100 mL (5 mg/mL); Levetiracetam in 0.75% Sodium Chloride Injection 1000 mg/100 mL (10 mg/mL); Levetiracetam in 0.54% Sodium Chloride Injection 1500 mg/100 mL (15 mg/mL)

Chemical Family : Pyrrolidine

Synonyms : (-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide

Manufacturer or supplier's details

Details of the Supplier of the Safety Data Sheet : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.

Emergency Telephone Number : +91-4467901901/02/03

Recommended use of the chemical and restrictions on use

Recommended use : Levetiracetam in Sodium Chloride Injection is indicated for adjunct therapy in adults (≥ 16 years of age) with the following seizure types when oral administration is temporarily not feasible:

- Partial-onset seizures
- Myoclonic seizures in patients with juvenile myoclonic epilepsy
- Primary generalized tonic-clonic seizures

Restrictions on use : Not applicable

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US) : Warning

Label elements

Hazard statements : H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements

P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Storage/Disposal : Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

Other Hazards : No data available

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS Number | Concentration (mg/mL) | | |
|---------------------------|-------------|-----------------------|-------------|-------------|
| Levetiracetam | 102767-28-2 | 5.0 | 10.0 | 15.0 |
| Sodium Chloride | 7647-14-5 | 8.2 | 7.5 | 5.4 |
| Glacial acetic acid | 64-19-7 | 0.055 | 0.065 | 0.075 |
| Sodium acetate trihydrate | 6131-90-4 | 1.64 | 1.64 | 1.64 |
| Glacial acetic acid | 64-19-7 | q.s to pH | q.s to pH | q.s to pH |
| Water for Injection | 7732-18-5 | q.s to 1 mL | q.s to 1 mL | q.s to 1 mL |

q.s – quantity sufficient

SECTION 4 : FIRST AID MEASURES

Inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

Skin : Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention

Eye : In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion : Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

Most important symptoms and effects, both acute and delayed

May cause redness and tearing of the eyes.
Burning sensation. May cause drowsiness or dizziness

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Notes to Physician : Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

SECTION 5 :FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Unsuitable Extinguishing Media : No data available

Special hazards arising from the substance or mixture

Fire Hazards : Product is not flammable

Explosive Hazard : Not an explosive

Reactivity : Hazardous reactions will not occur under normal conditions

Hazardous Combustion Products : Carbon oxides

Advice for firefighters

Precautionary measures in case of fire : Standard procedure for chemical fires

Firefighting instructions : Use water spray or fog; do not use straight streams

Protection of Firefighters : Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

SECTION 6 :ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personnel Precautions : Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

For non-emergency personnel

Personal Protective Equipment : Use personal protective equipment as required

Emergency Procedures : Evacuate personnel to safe areas.

For Emergency responders

Personal Protective Equipment: : Use personal protective equipment as required

Emergency Procedures : Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to

Environmental Precautions : Do not flush into surface water or sanitary sewer system. Should not be released into the environment. 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.

Methods for cleaning up : Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills: Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist

Prevention of secondary hazards : Clean contaminated objects and areas thoroughly observing environmental regulations

SECTION 7 : HANDLING AND STORAGE

Precautions of safe handling

Patients/ Consumers : Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Conditions for safe storage, including any incompatibilities

Storage : Store at 20° to 25°C (68° to 77°F)[see USP Controlled Room Temperature].

Specific end use : Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION

Control Parameters

Exposure Limits/
Guidelines : No information available

Exposure controls

Appropriate engineering controls : Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits

Personal Protective Equipment

| | |
|-------------|--|
| Respiratory | : Use appropriate respiratory protection |
| Eye/Face | : Safety glasses with side shields are recommended for medical or industrial exposures |
| Skin/Body | : Wear suitable protective clothing |
| Hands | : Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR |

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

Material Description

| | |
|------------------------|----------------------------|
| Physical form | : Liquid |
| Color | : Colorless |
| Odor Threshold | : No data available |
| Appearance/Description | : Clear colorless solution |
| Odor | : No data available . |

General Properties

| | |
|-------------------|----------------------|
| Boiling Point | : No data available |
| Melting Point | : Not relevant |
| pH | : Between 5.0 to 6.0 |
| Density | : 0.95 to 1.05 g/mL |
| Viscosity | : No data available |
| Specific Gravity/ | : No data available |
| Relative Density | |
| Water solubility | : No data available |

Decomposition Temperature : No data available

Volatility

Vapor Pressure : Not relevant

Vapor Density : Not relevant

Evaporation Rate : No data available

Flammability

Flash Point : Not relevant

UEL : Not relevant

LEL : Not relevant

Autoignition : Not relevant

Environmental

Octanol/Water Partition coefficient : No data available

SECTION 10 : Stability and Reactivity

Reactivity : Hazardous reactions will not occur under normal condition

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None under normal processing.

Conditions to avoid : Extremes of temperature and direct sunlight

Incompatible materials : Strong oxidizing agents, strong acids, and strong bases

Hazardous decomposition products : Decomposition will not occur under normal conditions.

SECTION 11 : TOXICOLOGICAL INFORMATION

Information On likely routes of exposure

Inhalation : Specific test data for the substance or mixture is not available

Eye Contact : May cause eye irritation.

Skin Contact : Specific test data for the substance or mixture is not available

Ingestion : Based on available data, the classification criteria are not met

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms : May cause redness and tearing of the eyes. Burning sensation.
: May cause drowsiness or dizziness

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation : Not classified
Serious eye damage/eye irritation : Not classified
Respiratory or skin sensitization: : Not classified
Germ cell mutagenicity: : Not classified
Carcinogenicity: : Not classified
Reproductive toxicity Not classified
STOT - single exposure Not classified
STOT - repeated exposure Not classified
Aspiration hazard Not classified

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity : No data available
Biodegradation : No data available
Bioaccumulation : No data available
Mobility in soil : No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system

| Chemical name | Weight-% | California Hazardous Waste Status |
|------------------------------|----------|-----------------------------------|
| Acetic Acid (CAS #: 64-19-7) | <0.1% | Toxic Corrosive Ignitable |

SECTION 14 : TRANSPORT INFORMATION

| | |
|------|---------------|
| DOT | Not regulated |
| ICAO | Not regulated |
| IATA | Not regulated |
| TDG | Not regulated |

SECTION 15: REGULATORY INFORMATION

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

U.S. Regulations:

TSCA – No

CERCLA-No

SARA 302 – No

SARA 311/312 – No

SARA 313 – No

OSHA - No

SECTION 16: ADDITIONAL INFORMATION

SDS creation date : Sep 02, 2024
SDS Revision date : NA
Version # : 00

Disclaimer:

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

---End of Safety Data Sheet---