Levetiracetam Injection and Levetiracetam in Sodium Chloride Injection
Safety Data Sheet

SECTION 1: Identification

1.1. Identification
Product name : Levetiracetam Injection
Other means of identification : NDC 55150-177-05

1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet
AuroMedics
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number
Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture
Classification (GHS-US)
STOT RE 2  H373
Full text of classification categories and H statements : see section 16

2.2. Label elements
GHS-US labeling
Hazard pictograms (GHS-US) :

Signal word (GHS-US) : Warning
Hazard statements (GHS-US) : H373 - May cause damage to organs through prolonged or repeated exposure
Precautionary statements (GHS-US) : 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.

2.3. Other hazards
No additional information available

2.4. Unknown acute toxicity (GHS US)
Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levetiracetam</td>
<td>(CAS No) 102767-28-2</td>
<td>10 (vials)</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5, 1, 1.5 (bags)</td>
<td>Eye Irrit. 2A, H319</td>
</tr>
</tbody>
</table>

Full text of classification categories and H statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures
First-aid measures after inhalation : If not breathing, give artificial respiration.
First-aid measures after skin contact : Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.
**Levetiracetam Injection and Levetiracetam in Sodium Chloride Injection Safety Data Sheet**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.2.</strong></td>
<td><strong>Most important symptoms and effects, both acute and delayed</strong></td>
</tr>
<tr>
<td>Symptoms/injuries after inhalation</td>
<td>None anticipated from normal handling of this product.</td>
</tr>
<tr>
<td>Symptoms/injuries after skin contact</td>
<td>None anticipated from normal handling of this product.</td>
</tr>
<tr>
<td>Symptoms/injuries after eye contact</td>
<td>Contact with eyes may produce irritation with redness and tearing.</td>
</tr>
<tr>
<td>Symptoms/injuries after ingestion</td>
<td>May be harmful if swallowed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4.3.</strong></td>
<td><strong>Indication of any immediate medical attention and special treatment needed</strong></td>
</tr>
<tr>
<td></td>
<td>No additional information available</td>
</tr>
</tbody>
</table>

**SECTION 5: Firefighting measures**

<table>
<thead>
<tr>
<th>subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.1.</strong></td>
<td><strong>Extinguishing media</strong></td>
</tr>
<tr>
<td>Suitable extinguishing media</td>
<td>Use extinguishing media appropriate for surrounding fire.</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None.</td>
</tr>
<tr>
<td><strong>5.2.</strong></td>
<td><strong>Special hazards arising from the substance or mixture</strong></td>
</tr>
<tr>
<td>Fire hazard</td>
<td>None known.</td>
</tr>
<tr>
<td><strong>5.3.</strong></td>
<td><strong>Advice for firefighters</strong></td>
</tr>
<tr>
<td>Protection during firefighting</td>
<td>During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.</td>
</tr>
</tbody>
</table>

**SECTION 6: Accidental release measures**

<table>
<thead>
<tr>
<th>subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.1.</strong></td>
<td><strong>Personal precautions, protective equipment and emergency procedures</strong></td>
</tr>
<tr>
<td>General measures</td>
<td>No special measures required.</td>
</tr>
<tr>
<td>For non-emergency personnel</td>
<td>No additional information available</td>
</tr>
<tr>
<td>For emergency responders</td>
<td>No additional information available</td>
</tr>
<tr>
<td><strong>6.2.</strong></td>
<td><strong>Environmental precautions</strong></td>
</tr>
<tr>
<td>Prevent entry to sewers and public waters.</td>
<td></td>
</tr>
<tr>
<td><strong>6.3.</strong></td>
<td><strong>Methods and material for containment and cleaning up</strong></td>
</tr>
<tr>
<td>For containment</td>
<td>Stop the flow of material, if this is without risk.</td>
</tr>
<tr>
<td>Methods for cleaning up</td>
<td>Collect spill with absorbent material. Clean spill area thoroughly.</td>
</tr>
<tr>
<td><strong>6.4.</strong></td>
<td><strong>Reference to other sections</strong></td>
</tr>
<tr>
<td>No additional information available</td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 7: Handling and storage**

<table>
<thead>
<tr>
<th>subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.1.</strong></td>
<td><strong>Precautions for safe handling</strong></td>
</tr>
<tr>
<td>Precautions for safe handling</td>
<td>Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.</td>
</tr>
<tr>
<td><strong>7.2.</strong></td>
<td><strong>Conditions for safe storage, including any incompatibilities</strong></td>
</tr>
<tr>
<td>Storage conditions</td>
<td>Store in a cool, dry place away from light.</td>
</tr>
</tbody>
</table>

**SECTION 8: Exposure controls/personal protection**

<table>
<thead>
<tr>
<th>subsection</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.1.</strong></td>
<td><strong>Control parameters</strong></td>
</tr>
<tr>
<td>Levetiracetam (102767-28-2)</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>8.2.</strong></td>
<td><strong>Exposure controls</strong></td>
</tr>
<tr>
<td>Appropriate engineering controls</td>
<td>Local exhaust and general ventilation must be adequate to meet exposure standards.</td>
</tr>
<tr>
<td>Hand protection</td>
<td>Not required for the normal use of this product. Wear protective gloves when working with large quantities.</td>
</tr>
</tbody>
</table>
Eye protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Wear suitable working clothes.

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

SECTION 9: Physical and chemical properties

9.1. Information on basic 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

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity: Not classified
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<table>
<thead>
<tr>
<th>Levetiracetam (102767-28-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATE US (oral)</td>
</tr>
</tbody>
</table>

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: 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.

Aspiration hazard: Not classified

SECTION 12: Ecological information

12.1. Toxicity
No additional information available

12.2. Persistence and degradability
No additional information available

12.3. Bioaccumulative potential
No additional information available

12.4. Mobility in soil
No additional information available

12.5. Other adverse effects
Effect on the global warming: No known effects from this product.
GWPmix comment: No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Waste disposal recommendations: Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)
In accordance with DOT
Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations
No additional information available

15.2. US State regulations
No additional information available

SECTION 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
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H373</td>
<td>May cause damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.