

Levetiracetam Injection and Levetiracetam in Sodium Chloride Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Levetiracetam Injection Levetiracetam in Sodim Chloride Injection
Other means of identification : NDC 55150-177-05 NDC 55150-246-47, NDC 55150-247-47, NDC 55150-248-47

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) :



GHS08

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

Name	Product identifier	%	Classification (GHS-US)
Levetiracetam	(CAS No) 102767-28-2	10 (vials) 0.5, 1, 1.5 (bags)	Acute Tox. 4 (Oral), H302 Eye Irrit. 2A, H319

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.

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First-aid measures after eye contact : Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

First-aid measures after ingestion : If signs of toxicity occur, seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : None anticipated from normal handling of this product.

Symptoms/injuries after skin contact : None anticipated from normal handling of this product.

Symptoms/injuries after eye contact : Contact with eyes may produce irritation with redness and tearing.

Symptoms/injuries after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Collect spill with absorbent material. Clean spill area thoroughly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a cool, dry place away from light.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Levetiracetam (102767-28-2)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Not required for the normal use of this product. Wear protective gloves when working with large quantities.

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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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ATE US (oral)	500.000 mg/kg body weight
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

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H319	Causes serious eye irritation
H373	May cause damage to organs through prolonged or repeated exposure

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