



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET

Product Name	Levetiracetam Injection USP 500 mg/5 mL	Page No 1 of 4
---------------------	--	-----------------------

1. Identification of the substance/mixture and the company/undertaking

Product Name: Levetiracetam Injection USP 500 mg/5 mL

Chemical Family: Mixture

Intended use: Antiepileptic

Details of the manufacturer:

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. Hazards Identification

- | | | |
|------------|----------------------------|--|
| 2.1 | Fire and Explosion: | Expected to be non-combustible |
| 2.2 | Health: | None |
| 2.3 | Environment: | No information is available about the potential of this product to produce adverse environmental effects |

3. Composition/Information on Ingredients

C.A.S. No : 102767-28-2
Molecular Formula : $C_8H_{14}N_2O_2$
Molecular Weight : 170.212 g/mol
Chemical Name : (2S)-2-(2-oxopyrrolidin-1-yl)butanamide

4. First Aid Measures

4.1 Description of first aid measures

Eye contact

Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

Skin contact

Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

Inhalation

Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion

Wash out mouth with water; give water to drink and induce vomiting; call a physician.

SAFETY DATA SHEET**Product Name** Levetiracetam Injection USP 500 mg/5 mL**Page No 2 of 4****5.0 Fire Fighting Measures****5.1 Fire and Explosion Hazards:**

Assume that this product is capable of sustaining combustion.

5.2 Extinguishing media

Suitable extinguishing media

Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

5.3 Special hazards arising from the substance or mixture

During combustion, may emit irritant fumes.

5.4 Advice for firefighters

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.

5.5 Further information

no data available

6. Accidental Release Measures**6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

7. Handling and Storage**7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

7.2 Storage Conditions: Store at 25°C (77°F); excursions permitted to 15°C – 30°C (59°F - 86°F).
[See USP Controlled Room Temperature]**8. Exposure Controls/Personal Protection****8.1 Control parameters**

Components with workplace control parameters

8.2 Exposure controls**8.2.1 Appropriate engineering controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

FDQA CONTROLLED COPY

SAFETY DATA SHEET

Product Name	Levetiracetam Injection USP 500 mg/5 mL	Page No 3 of 4
---------------------	--	-----------------------

8.2.2 Personal protective equipment**8.2.2.1 Eye/face protection**

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166(EU).

8.2.2.2 Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.

Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

8.2.2.3 Body Protection

impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

8.2.2.4 Respiratory protection

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges.

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.2.5 Control of environmental exposure

Do not let product enter drains.

9. Physical and Chemical Properties

Appearance : Clear colorless solution.

10. Stability and Reactivity**10.1 Reactivity**

no data available

10.2 Chemical stability

Stable under recommended storage conditions.

11. Toxicological Information**11.1 Carcinogenesis :**

Rats were dosed with levetiracetam in the diet for 104 weeks at doses of 50, 300 and 1800 mg/kg/day. The highest dose is 6 times the maximum recommended daily human dose (MRHD) of 3000 mg on a mg/m² basis and it also provided systemic exposure (AUC) approximately 6 times that achieved in humans receiving the MRHD. There was no evidence of carcinogenicity. In mice, oral administration of levetiracetam for 80 weeks (doses up to 960 mg/kg/day) or 2 years (doses up to 4000 mg/kg/day, lowered to 3000 mg/kg/day after 45 weeks due to intolerability) was not associated with an increase in tumors. The highest dose tested in mice for 2 years (3000 mg/kg/day) is



SAFETY DATA SHEET

Product Name Levetiracetam Injection USP 500 mg/5 mL

Page No 4 of 4

approximately 5 times the MRHD on a mg/m² basis.

11.2 Mutagenesis :

Levetiracetam was not mutagenic in the Ames test or in mammalian cells in vitro in the Chinese hamster ovary/HGPRT locus assay. It was not clastogenic in an in vitro analysis of metaphase chromosomes obtained from Chinese hamster ovary cells or in an in vivo mouse micronucleus assay. The hydrolysis product and major human metabolite of levetiracetam (ucb L057) was not mutagenic in the Amestest or the in vitro mouse lymphoma assay.

11.3 Impairment of Fertility :

No adverse effects on male or female fertility or reproductive performance were observed in rats at oral doses up to 1800 mg/kg/day (6 times the maximum recommended human dose on a mg/m² or systemic exposure [AUC] basis).

12. Ecological Information

Not applicable

13. Disposal Considerations

13.1 Waste treatment methods

Product: Burn in a chemical incinerator equipped with an afterburner and scrubber but exert extra care in igniting. Offer surplus and nonrecyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

Contaminated packaging: Dispose of as unused product.

14. Transport Information

Not dangerous goods by U.S. DOT, IMDG and IATA

15. Regulatory Information

5.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
no data available

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

16. Other Information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MSN Laboratories Pvt. Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.

FDQA CONTROLLED COPY