



**MSN**

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

**SAFETY DATA SHEET**

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**Product Name** BRIVARACETAM INJECTION 50 mg/5 mL (10 mg/mL)

**1. Product Information**

**Product Name : BRIVARACETAM INJECTION 50 mg/5 mL (10 mg/mL)**

**Chemical Family:** Mixture

**Intended use:** Pharmaceutical product is Treatment of partial-onset seizures in patients 4 years of age and older.

**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**

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

**3. Composition/Information on Ingredients**

C.A.S. No : 357336-20-0

Molecular Formula :  $C_{11}H_{20}N_2O_2$

Molecular Weight : 212.29

Chemical Name : (2S)-2-[(4R)-2-oxo-4-propyltetrahydro-1H-pyrrol-1-yl] butanamide

**4. First Aid Measures**

**Eye Contact:** Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

**Skin Contact:** flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

**Ingestion:** If swallowed, wash out mouth with copious amounts of water; call a physician.

**Inhalation:** If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

**5. Fire Fighting Measures**

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

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**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

**Fire / Explosion Hazards:** Not applicable

#### 6. Accidental Release Measures

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Measures for Environmental Protections:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:**

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

#### 7. Handling and Storage

**General Handling:** Minimize dust generation and accumulation. Avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

**Storage Conditions:** Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP controlled Room Temperature]. Do not freeze

#### 8. Exposure Controls/Personal Protection

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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**9. Physical and Chemical Properties**

**Appearance :** Clear, colorless, sterile solution supplied in colorless single-dose glass vials

**10. Stability and Reactivity**

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** None known

**11. Toxicological Information**

**Acute toxicity:** no data available

**Skin corrosion/irritation:** no data available

**Serious eye damage/eye irritation:** no data available

**Respiratory or skin sensitization:** no data available

**Germ cell mutagenicity:** no data available

**Potential Health Effects**

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.

**Skin:** May be harmful if absorbed through skin. May cause skin irritation.

**Eyes:** May cause eye irritation.

**Ingestion:** May be harmful if swallowed.

**Signs and Symptoms of Exposure:** To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

**Synergistic effects:** no data available

**Additional information:** RTECS: not

**12. Ecological Information**

**Persistence and degradability:** No data available

**Toxicity:** No data available

**Bioaccumulative potential:** No data available

**Mobility in soil:** No data available

**PBT and vPvB assessment:** No data available

**Other adverse effects:** No data available

**13. Disposal Considerations**

**Product :** Dispose of in accordance with local authority regulations.

**Contaminated packaging :** Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.

**14. Transport Information**

**DOT (US):** Not dangerous goods.

**IMDG:** Not dangerous goods.

**IATA:** Not dangerous goods.

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**15. Regulatory Information**

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

**16. Other Information**

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.