



MATERIAL SAFETY DATA SHEET

LEVETIRACETAM INJECTION USP 500MG/5ML

1. IDENTIFICATION

Material Identification	:	Levetiracetam Injection USP 500mg/5ml		
Active ingredient	:	(-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide		
Molecular Formula	:	$C_8H_{14}N_2O_2$	Molecular Weight	: 170.2 g/mol
CAS Number	:	102767-28-2		
Product Use	:	Anti-Convulsants		
Manufactured by	:	Micro Labs Limited Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	Manufactured for	: Armas Pharmaceuticals Inc. 151 Route 33 East, Suite 203, Manalapan, NJ 07726
Emergency Contact	:	+91-80-27839033		

2. HAZARDS IDENTIFICATION

Label Elements

Signal	:	 Warning
Physical hazards	:	Not classified
Classification of the substance	:	Not classifiable
Hazard statements	:	Causes damage to organs through prolonged or repeated exposure. Suspected of damaging fertility or the unborn child. May cause an allergic skin reaction. May cause drowsiness or dizziness. May cause harmful to breast-fed children. May causes serious eye irritation.
Precautionary statements	:	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid contact during pregnancy and while nursing. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area.



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Precautionary statements	<p>: Contaminated work clothing should not be allowed out of the work place. Contaminated clothes should be washed before reuse. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If on skin: wash with plenty of water. If skin irritation or rashes occur: Get medical advice. If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If exposed or concerned: Get medical advice/attention. Call a Poison Centre or Doctor/Physician if you feel unwell. Store in well ventilated place. Keep container tightly closed. Dispose of contents/container in accordance with local/regional/national/international regulations.</p>
Supplementary Information	<p>: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.</p>
Hazard(s) not otherwise classified (HNOC)	<p>: Not known.</p>

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS #	EINECS #	% w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Active Pharmaceutical Ingredient				
Levetiracetam Hydrochloride (-)-(S)- α -ethyl-2-oxo-1-pyrrolidine acetamide	102767-28-2	Not listed	Proprietary	EU 67/548/EEC: Not listed under European Union Legislation GHS & EU 1272/2008: Classification: Acute oral toxicity Category 4, Hazard codes: H302: Harmful if swallowed. H319: Causes serious eye irritation.



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Chemical Name	CAS #	EINECS #	% w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Excipients				
Sodium Chloride Inj. Grade	7647-14-5	231-598-3	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Not Classified
Sodium Acetate trihydrate (Inj. Grade)	6131-90-4	Not Listed	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Not classified
Glacial Acetic Acid	64-19-7	200-580-7	Proprietary	EU 67/548/EEC: Classification: Not classified under European Union Legislation GHS & EU 1272/2008: Classification: Skin Corrosion 1A H314: Causes severe skin burns and eye damage. Flam. Liq.3 H226: Flammable liquid and vapour.
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.				
4. FIRST AID MEASURES				
Eyes Contact	:	Remove from source of exposure. Move individual(s) to fresh air. Check for and remove any contact lenses, if easy to do. Flush with copious amounts of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Effects of exposure may be delayed. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.		
Skin Contact	:	The risk of skin contact is negligible when the product is in its final packaged form. Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Immediately wash skin with plenty of soap and copious amounts of water for at least 15 to 20 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.		



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Ingestion	:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water if person is conscious. Keep victim warm and quiet. Loosen tight clothing such as a collar, tie, belt or waistband. Never give anything by mouth to an unconscious person. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Do NOT induce vomiting unless directed to do so by medical personnel. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. Effects of exposure (ingestion) to substance may be delayed.
Inhalation	:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If breathing is difficult, give oxygen. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	:	Use personal protective equipment.
Signs and Symptoms:	:	Contact with eyes may produce irritation with redness and tearing. May be harmful if swallowed.
Medical Conditions Aggravated by Exposure:	:	None Known
Notes to Physician:	:	Seek product package insert for complete information.
General information	:	Remove from exposure. Remove contaminated clothing. For treatment advice, get the guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media	:	Use alcohol resistant foam, Carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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General Information:

As in any fire, wear self-contained breathing apparatus and full protective gear. Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize the risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.



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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing. For personal protection see section 8.
Environmental precautions	:	Avoid runoff into storm sewers, ditches and waterways. Contain material and prevent release to basements, confined spaces, waterways or soil.
Methods and material for containment and cleaning up	:	Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

7. HANDLING AND STORAGE

Precautions for safe handling	:	Prevent static charge when handling the material. Handle in accordance with product label and/or product insert information. Avoid dust generation or accumulation. Use mechanical ventilation to control dust. Do not wear contaminated clothing. Wash prior to eating, drinking, smoking or use of restroom and when leaving work. Do not dispose of material or empty container into the environment.
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Conditions for safe storage, including any incompatibilities

Storage conditions	:	Store at 25°C (77°F) Excursions Permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature)
Specific end use(s)	:	Pharmaceutical drug product for patients

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls	:	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.
Personal Protective Equipment	:	Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. In laboratory, medical or industrial settings: Safety glasses with side shields. Lab coat. Gloves.



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Respirator. Be sure to use an approved/ certified respirator or equivalent.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection	:	<p>Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)</p> <p>Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).</p> <p>Not required during normal clinical use.</p>
Hands	:	<p>Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)</p> <p>For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.</p>
Eye Protection	:	<p>Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or EN166 standards) is preferred. Maintain eyewash facilities in the work area. Appropriate eye protection is required when handling bulk liquids.</p>
Skin protection	:	<p>Wear protective laboratory coat, apron, or disposable garment when working with large quantities.</p> <p>Not required during normal clinical use. Wash thoroughly with warm water and soap after handling. Impervious gloves are recommended when directly handling bulk liquids.</p>

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	:	Solution for Injection
Color	:	Clear, colorless solution
Appearance	:	Levetiracetam Injection USP 500mg/5ml: Clear, colorless to nearly colorless, slightly viscous solution, free from any visible particles.
Molecular Formula	:	$C_8H_{14}N_2O_2$
Molecular Weight	:	170.2 g/mol



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10. STABILITY AND REACTIVITY

Reactivity	:	Not Available
Conditions to Avoid	:	Not Available
Incompatible Materials	:	Keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	:	Levetiracetam:			
		Type	Route	Species	Dosage
		LD50	Intravenous	Rat	1038 mg/kg
		LD50	Intravenous	Mouse	1081 mg/kg
		LD50	Oral	Rat	>5g/kg
		LD50	Oral	Mouse	>5g/kg
		Sodium Chloride:			
		LD50	Oral	Rat	3g/kg
		LD50	Dermal	Rabbit	>10g/kg
		LD50,1 hour	Inhalation	Rat	>42g/m ³
Water:					
LD50	Oral	Rat	>90 ml/kg		
Skin Irritation/ Sensitization	:	May cause skin irritation.			
Eye irritation	:	May cause eye irritation.			
Germ cell mutagenicity	:	No data available			
Carcinogenicity	:	Not Carcinogenic			
IARC:	:	Not considered to be a carcinogen.			
NTP:	:	Not considered to be a carcinogen.			
OSHA:	:	Not considered to be a carcinogen.			
Reproductive toxicity:	:	No data available			



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12. ECOLOGICAL INFORMATION

Toxicity:	: Water flea (<i>Daphnia magna</i>) – EC50 48 h: 340.7 – 469.2 mg/L Static Fish <i>Oncorhynchus mykiss</i> – LC50 96h: 4747-7824 mg/L flow-through <i>Lepomis macrochirus</i> – LC50 96h: 5560-6080 mg/L flow-through <i>Pimephales promelas</i> – LC50 96h: 6020-7070 mg/L static <i>Pimephales promelas</i> – LC50 96h: 6420-6700 mg/L static <i>Lepomis macrochirus</i> – LC50 96h: 12946 mg/L static <i>Pimephales promelas</i> – LC50 96h: 7050 mg/L semistatic
Persistence and degradability	: No data available
Bioaccumulative potential	: The low partition coefficient n-octanol/water indicates that it is unlikely to concentrate in biosolids (sewage sludge) or aquatic sediments. Its potential to bioaccumulate or bioconcentrate in the environment is negligible.
Mobility in soil	: No data available
Results of PBT and vPvB	: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods	: All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.
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14. TRANSPORTATION INFORMATION

Environmental hazards	: No data available
Special precautions for user	: No data available
Transport hazard class(es)	: Not applicable
Packing group	: Not applicable
IATA UN number	: Not applicable

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.



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15. REGULATORY / STATUTORY INFORMATION

Seveso regulation (Directive 96/82/EC)	:	Not Available
Candidate list (art. 59-REACH):	:	Not Available
Ozone depletion substance (2000/2037/EC)	:	Not Available
Import/export dangerous chemical (2008/689/EC)	:	Not Available

16. OTHER INFORMATION

Date of preparation: 20/11/20

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet